Replacement

ROUTING RECORD

DATE	FROM	TO	ACTION
6-9-17	JT07	CW02	I
9/1/2017	CW02	JT07	PC/PO Rec
9-8-17	JT07	RS	Approved PC/PO

REFERENCE OTHER APCD RECORDS INCLUDING VAR...

Permit No. G48221

APPL # 594738
I.D. # 103609

ST. JUDE MEDICAL CRMD
15900 VALLEY VIEW CT
SYLMAR
ETHYLENE OXIDE STERILIZER

Date: 08/08/17

ST. JUDE MEDICAL CRMD
ETHYLENE OXIDE STERILIZER

AP 594738
ID 103609

South Coast Air Quality Management District

Form 400-A

Application Form for Permit or Plan Approval

List only one piece of equipment or process per form.

Mail To:
SCAQMD
P.O. Box 4944
Diamond Bar, CA 91765-0944

Tel: (909) 396-3385
www.aqmd.gov

Section A - Operator Information

1. Facility Name (Business Name of Operator to Appear on the Permit): St. Jude Medical CRMD

2. Valid AQMD Facility ID (Available On Permit Or Invoice Issued By AQMD): 103609

3. Owner's Business Name (If different from Business Name of Operator):

Section B - Equipment Location Address

4. Equipment Location Is: (◉) Fixed Location ( ) Various Location
(For equipment operated at various locations, provide address of initial site.)

15900 Valley View Ct
Street Address
Sylmar , CA 91342
City Zip
Mike Larson Facilities Director
Contact Name Title
(818) 493-3490 Ext. (818) 256-8327
Phone # Fax #
E-Mail: mlarson@sjm.com

Section C - Permit Mailing Address

5. Permit and Correspondence Information:
[X] Check here if same as equipment location address

15900 Valley View Ct
Address
Sylmar , CA 91342
City State Zip
Omar Elfar Consultant
Contact Name Title
(949) 567-9880 Ext. (949) 567-9894
Phone # Fax #
E-Mail: oelfar@trinityconsultants.com

Section D - Application Type

6. The Facility Is: (◉) Not In RECLAIM or Title V ( ) In RECLAIM ( ) In Title V ( ) In RECLAIM & Title V Programs

7. Reason for Submitting Application (Select only ONE):

7a. New Equipment or Process Application:
(◉) New Construction (Permit to Construct) 10
( ) Equipment On-Site But Not Constructed or Operational
( ) Equipment Operating Without A Permit *
( ) Compliance Plan
( ) Registration/Certification
( ) Streamlined Standard Permit

7b. Facility Permits:
( ) Title V Application or Amendment (Refer to Title V Matrix)
( ) RECLAIM Facility Permit Amendment

7c. Equipment or Process with an Existing/Previous Application or Permit:
( ) Administrative Change
( ) Alteration/Modification
( ) Alteration/Modification without Prior Approval *
( ) Change of Condition
( ) Change of Condition without Prior Approval *
( ) Change of Location
( ) Change of Location without Prior Approval *
( ) Equipment Operating with an Expired/Inactive Permit *

Existing or Previous Permit/Application
If you checked any of the items in 7c., you MUST provide an existing Permit or Application Number:

* A Higher Permit Processing Fee and additional Annual Operating Fees (up to 3 full years) may apply (Rule 301(c)(1)(D)(i)).

8a. Estimated Start Date of Construction (mm/dd/yyyy): 12/01/2017
8b. Estimated End Date of Construction (mm/dd/yyyy): 12/31/2017
8c. Estimated Start Date of Operation (mm/dd/yyyy): 01/01/2018

9. Description of Equipment or Reason for Compliance Plan (list applicable rule): Ethylene Oxide Sterilizer

10. For Identical equipment, how many additional applications are being submitted with this application? (Form 400-A required for each equipment / process)

11. Are you a Small Business as per AQMD's Rule 102 definition? (10 employees or less and total gross receipts are $500,000 or less OR a not-for-profit training center) (◉) No ( ) Yes

12. Has a Notice of Violation (NOV) or a Notice to Comply (NC) been issued for this equipment? (◉) No ( ) Yes
If Yes, provide NOV/NC#:

Section E - Facility Business Information

13. What type of business is being conducted at this equipment location? Manufacturer of Medical Devices

14. What is your business primary NAICS Code? (North American Industrial Classification System) 334510

15. Are there other facilities in the SCAQMD jurisdiction operated by the same operator? (◉) No ( ) Yes

16. Are there any schools (K-12) within 1000 feet of the facility property line? (◉) No ( ) Yes

Section F - Authorization/Signature

I hereby certify that all information contained herein and information submitted with this application are true and correct.

17. Signature of Responsible Official: Mike Larson

18. Title of Responsible Official: Facilities Director

19. I wish to review the permit prior to issuance. (This may cause a delay in the application process.) ( ) No (◉) Yes

20. Print Name: Mike Larson

21. Date: 5-22-17

22. Do you claim confidentiality of data? (If Yes, see instructions.) (◉) No ( ) Yes

23. Check List: [X] Authorized Signature/Date [X] Form 400-CEQA [X] Supplemental Form(s) (ie., Form 400-E-xx) [X] Fees Enclosed

AQMD USE ONLY	APPLICATION TRACKING #	CHECK #	AMOUNT RECEIVED	PAYMENT TRACKING #	VALIDATION
	594738	158203	$ 3,927.10	134411	6/16/17

DATE	APP REJ	DATE	APP REJ	CLASS I III	BASIC CONTROL	EQUIPMENT CATEGORY CODE	TEAM	ENGINEER	REASON/ACTION TAKEN
						000289	8		

South Coast Air Quality Management District

Form 400-CEQA

California Environmental Quality Act (CEQA) Applicability

Mail To:
SCAQMD
P.O. Box 4944
Diamond Bar, CA 91765-0944

Tel: (909) 396-3385
www.aqmd.gov

The SCAQMD is required by state law, the California Environmental Quality Act (CEQA), to review discretionary permit project applications for potential air quality and other environmental impacts. This form is a screening tool to assist the SCAQMD in clarifying whether or not the project[1] has the potential to generate significant adverse environmental impacts that might require preparation of a CEQA document [CEQA Guidelines §15060(a)].[2] Refer to the attached instructions for guidance in completing this form.[3] For each Form 400-A application, also complete and submit one Form 400-CEQA. If submitting multiple Form 400-A applications for the same project at the same time, only one 400-CEQA form is necessary for the entire project. If you need assistance completing this form, contact Permit Services at (909) 396-3385 or (909) 396-2668.

Section A - Facility Information

1. **Facility Name** (Business Name of Operator To Appear On The Permit): St. Jude Medical CRMD

2. **Valid AQMD Facility ID** (Available On Permit Or Invoice Issued By AQMD): 103609

3. **Project Description:** Construction of ethylene oxide sterilizer

Section B - Review For Exemption From Further CEQA Action

Check "Yes" or "No" as applicable

	Yes	No	Is this application for:
1.	○	◉	**A CEQA and/or NEPA document previously or currently prepared that specifically evaluates this project?** If yes, attach a copy of the signed Notice of Determination to this form.
2.	○	◉	**A request for a change of permittee only (without equipment modifications)?**
3.	◉	○	**A functionally identical permit unit replacement with no increase in rating or emissions?**
4.	○	◉	**A change of daily VOC permit limit to a monthly VOC permit limit?**
5.	○	◉	**Equipment damaged as a result of a disaster during state of emergency?**
6.	○	◉	**A Title V (i.e., Regulation XXX) permit renewal (without equipment modifications)?**
7.	○	◉	**A Title V administrative permit revision?**
8.	○	◉	**The conversion of an existing permit into an initial Title V permit?**

If "Yes" is checked for any question in Section B, your application does not require additional evaluation for CEQA applicability. Skip to Section D - Signatures on page 2 and sign and date this form.

Section C - Review of Impacts Which May Trigger CEQA

Complete Parts I-VI by checking "Yes" or "No" as applicable. To avoid delays in processing your application(s), explain all "Yes" responses on a separate sheet and attach it to this form.

	Yes	No	Part I - General
1.	○	○	**Has this project generated any known public controversy regarding potential adverse impacts that may be generated by the project?** Controversy may be construed as concerns raised by local groups at public meetings; adverse media attention such as negative articles in newspapers or other periodical publications, local news programs, environmental justice issues, etc.
2.	○	○	**Is this project part of a larger project?** If yes, attach a separate sheet to briefly describe the larger project.
			Part II - Air Quality
3.	○	○	**Will there be any demolition, excavating, and/or grading construction activities that encompass an area exceeding 20,000 square feet?**
4.	○	○	**Does this project include the open outdoor storage of dry bulk solid materials that could generate dust?** If Yes, include a plot plan with the application package.

[1] A "project" means the whole of an action which has a potential for resulting in physical change to the environment, including construction activities, clearing or grading of land, improvements to existing structures, and activities or equipment involving the issuance of a permit. For example, a project might include installation of a new, or modification of an existing internal combustion engine, dry-cleaning facility, boiler, gas turbine, spray coating booth, solvent cleaning tank, etc.

[2] To download the CEQA guidelines, visit http://ceres.ca.gov/env_law/state.html.

[3] To download this form and the instructions, visit http://www.aqmd.gov/ceqa or http://www.aqmd.gov/permit

Section C - Review of Impacts Which May Trigger CEQA (cont.)			
	Yes	No	Part II - Air Quality (cont.)
5.	○	○	**Would this project result in noticeable off-site odors from activities that may not be subject to SCAQMD permit requirements?** For example, compost materials or other types of greenwaste (i.e., lawn clippings, tree trimmings, etc.) have the potential to generate odor complaints subject to Rule 402 – Nuisance.
6.	○	○	**Does this project cause an increase of emissions from marine vessels, trains and/or airplanes?**
7.	○	○	**Will the proposed project increase the QUANTITY of hazardous materials stored aboveground onsite or transported by mobile vehicle to or from the site by greater than or equal to the amounts associated with each compound on the attached Table 1?[4]**
			Part III – Water Resources
8.	○	○	**Will the project increase demand for water at the facility by more than 5,000,000 gallons per day?** The following examples identify some, but not all, types of projects that may result in a "yes" answer to this question: 1) projects that generate steam; 2) projects that use water as part of the air pollution control equipment; 3) projects that require water as part of the production process; 4) projects that require new or expansion of existing sewage treatment facilities; 5) projects where water demand exceeds the capacity of the local water purveyor to supply sufficient water for the project; and 6) projects that require new or expansion of existing water supply facilities.
9.	○	○	**Will the project require construction of new water conveyance infrastructure?** Examples of such projects are when water demands exceed the capacity of the local water purveyor to supply sufficient water for the project, or require new or modified sewage treatment facilities such that the project requires new water lines, sewage lines, sewage hook-ups, etc.
			Part IV – Transportation/Circulation
10.			**Will the project result in** (Check all that apply)**:**
	○	○	**a. the need for more than 350 new employees?**
	○	○	**b. an increase in heavy-duty transport truck traffic to and/or from the facility by more than 350 truck round-trips per day?**
	○	○	**c. increase customer traffic by more than 700 visits per day?**
			Part V – Noise
11.	○	○	**Will the project include equipment that will generate noise GREATER THAN 90 decibels (dB) at the property line?**
			Part VI – Public Services
12.			**Will the project create a permanent need for new or additional public services in any of the following areas** (Check all that apply)**:**
	○	○	**a. Solid waste disposal?** Check "No" if the projected potential amount of wastes generated by the project is less than five tons per day.
	○	○	**b. Hazardous waste disposal?** Check "No" if the projected potential amount of hazardous wastes generated by the project is less than 42 cubic yards per day (or equivalent in pounds).

REMINDER: *For each "Yes" response in Section C, attach all pertinent information including but not limited to estimated quantities, volumes, weights, etc.*

Section D - Signatures

I HEREBY CERTIFY THAT ALL INFORMATION CONTAINED HEREIN AND INFORMATION SUBMITTED WITH THIS APPLICATION IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE. I UNDERSTAND THAT THIS FORM IS A SCREENING TOOL AND THAT THE SCAQMD RESERVES THE RIGHT TO CONSIDER OTHER PERTINENT INFORMATION IN DETERMINING CEQA APPLICABILITY.

1. Signature of Responsible Official of Firm:		2. Title of Responsible Official of Firm:
		Facilities Director
3. Print Name of Responsible Official of Firm:		4. Date Signed:
Mike Larson		5-22-17
5. Phone # of Responsible Official of Firm:	6. Fax # of Responsible Official of Firm:	7. Email of Responsible Official of Firm:
(818) 493-3490	(818) 256-8327	mlarson@sjm.com
8. Signature of Preparer, (If prepared by person other than responsible official of firm):		9. Title of Preparer:
10. Print Name of Preparer:		11. Date Signed:
12. Phone # of Preparer:	13. Fax # of Preparer:	14. Email of Preparer:

THIS CONCLUDES FORM 400-CEQA. INCLUDE THIS FORM AND ANY ATTACHMENTS WITH FORM 400-A.

[4] Table 1 – Regulated Substances List and Threshold Quantities for Accidental Release Prevention can be found in the Instructions for Form 400-CEQA.

South Coast Air Quality Management District

Form 400-E-8
Ethylene Oxide Sterilizer

Mail To:
SCAQMD
P.O. Box 4944
Diamond Bar, CA 91765-0944

Tel: (909) 396-3385
www.aqmd.gov

This form must be accompanied by a completed Application for a Permit to Construct/Operate - Forms 400-A, Form 400-CEQA, and Form 400-PS.

Section A - Operator Information

Facility Name (Business Name of Operator That Appears On Permit): St. Jude Medical CRMD

Valid AQMD Facility ID (Available On Permit Or Invoice Issued By AQMD): 103609

Address where the equipment will be operated (for equipment which will be moved to various location in AQMD's jurisdiction, please list the initial location site): 15900 Valley View Ct, Sylmar, CA 91342

(●) Fixed Location ( ) Various Locations

Section B - Equipment Description

Equipment	Manufacturer: Getinge	Model: GEE101420 - 1	Serial No.: TBD
Internal Dimensions of Sterilizer Chamber	Width: 3 ft. 3.4 in.	Length: 6 ft. 6.7 in.	Height: 4 ft. 9.1 in.
Sterilizer Heater Information	Operating Temperature: 120 °F	a. (●) Electric: 100 KW b. ( ) Gas: _____ BTU/hr	c. ( ) Steam d. ( ) Other (specify): _____
Sterilizer Exhaust Blower Information	Capacity: 1000 ACFM		
Internal Dimensions of Aeration Chamber	Width: _____ ft. _____ in.	Length: _____ ft. _____ in.	Height: _____ ft. _____ in.
Aeration Heater Information	Operating Temperature: _____ °F	a. ( ) Electric: _____ KW b. ( ) Gas: _____ BTU/hr	c. ( ) Steam d. ( ) Other (specify): _____
Aeration Exhaust Blower Information	Capacity: _____ ACFM		

Section C - Operation Information

Sterilant Gas Information

a. Composition

Ethylene Oxide (ETO):	% by weight:
Ethylene Oxide	100.00

b. Maximum Temperature: 122 °F

c. Pressure: 5 psi

Sterilizer Vented Information

Is Sterilizer vented to an external Air Pollution Control (APC) equipment?

a. ( ) No

b. (●) Yes; Please Indicate Type of Control

- [x] Catalytic Afterburner
- [ ] Condensation/Reclamation
- [ ] Acid-water Scrubber
- [ ] Other [1]

[1] A separate permit is required

South Coast Air Quality Management District

Form 400-E-8
Ethylene Oxide Sterilizer

This form must be accompanied by a completed Application for a Permit to Construct/Operate - Forms 400-A, Form 400-CEQA, and Form 400-PS.

Section C - Operation Information (cont.)

Process Information

Weight of ETO: 3 lbs/load Average Usage: 3 loads/day

Maximum Usage: 5 loads/day

Operating Schedule

Normal:	24 hours/day	5 days/week	52 weeks/yr
Maximum:	24 hours/day	7 days/week	52 weeks/yr

Section D - Authorization/Signature

I hereby certify that all information contained herein and information submitted with this application is true and correct.

Preparer Info

Signature: [signature] Date: 5-22-17

Title: Facilities Director Company Name: St. Jude Medical

Name: Mike Larson

Phone #: (818) 493-3490 Fax #: (818) 256-8327

Email: mlarson@sjm.com

Contact Info

Name:

Title: Company Name:

Phone #: Fax #:

Email:

THIS IS A PUBLIC DOCUMENT

Pursuant to the California Public Records Act, your permit application and any supplemental documentation are public records and may be disclosed to a third party. If you wish to claim certain limited information as exempt from disclosure because it qualifies as a trade secret, as defined in the District's Guidelines for Implementing the California Public Records Act, you must make such claim at the time of submittal to the District.

Check here if you claim that this form or its attachments contain confidential trade secret information. ☐

SCAQM_ . ERMIT PROCESSING SYSTEM (. . S)

FEE DATA - SUMMARY SHEET

Application No : **594738** IRS/SS No:

Previous Application No: Previous Permit No:

Company Name : **ST. JUDE MEDICAL CRMD** Facility ID: **103609**

Equipment Street: **15900 VALLEY VIEW CT , SYLMAR CA 91342**

Equipment Desc : **STERILIZING EQUIPMENT**

Equipment Type : **BASIC** Fee Charged by: **B-CAT**

B-CAT NO. : **000289** C-CAT NO: **00** Fee Schedule: **C**

Facility Zone : **06** Deemed Compl. Date: **6/6/2017** Public Notice: **NO**

Evaluation Type : **PERMIT TO CONSTRUCT/OPERATE (PC/PO)** Small Business: ☐

Disposition : **Approve PC/PO, Recommended by Engineer** Higher Fees for Failing to Obtain a Permit: ☐

Lead Appl. No : Identical Permit Unit: ☐

Air quality Analysis			$0.00	Filing Fee Paid:	$0.00
E.I.R			$0.00	Permit Processing Fee Paid:	$3,927.10
Health Risk Assessment			$0.00	Permit Processing Fee Calculated*:	$3,927.10
Public Notice Preparation Fee			$0.00	Permit Processing Fee Adjustment:	$0.00
Public Notice Publication Fee			$0.00		
Expedited Processing	Hours:	0.00	$0.00		
Source Test Review	Hours:	0.00	$0.00		
Time & Material	Hours:	0.00	$0.00		
				Total Additional Fee:	$0.00
				Additional Charge:	$0.00

COMMENTS:

RECOMMENDED BY: **CAROLYN D WILEY** DATE: **09/01/2017**

REVIEWED BY: _____ DATE: 9/8/17

* ADJUSTED FOR SMALL BUSINESS, IDENTICAL EQUIPMENT AND P/O NO P/C PENALTY

SCAQMD PERMIT PROCESSING SYSTEM (PPS)

AEIS DATA SHEET

Company Name : ST. JUDE MEDICAL CRMD
Facility ID : 103609
Equipment Address : 15900 VALLEY VIEW CT
SYLMAR CA 91342

Application Number : 594738
Equipment B-Cat : 000289
Estimated Completion Date : 09/01/17
Equipment C-Cat :
Equipment Type : Basic
Equipment Description : STERILIZING EQUIPMENT

	Emissions	
Emittants	R1 LB/HR	R2 LB/HR
ROG	0.01	0.01

Applicable Rules

1405	01/04/1991	ETO & CFC From Sterilization & Fumigation

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Daily Start Times :	08:00	08:00	08:00	08:00	08:00	00:00	00:00
Daily Stop Times :	24:00	24:00	24:00	24:00	24:00	00:00	00:00

User's Initials : CW02 Date: 09/01/17 Supervisor's Name : S.T. Review Date : 9/8/17

PERMIT TO CONSTRUCT/OPERATE

This initial permit must be renewed ANNUALLY unless the equipment is moved, or changes ownership.
If the billing for the annual renewal fee (Rule 301.f) is not received by the expiration date, contact the District.

Legal Owner or Operator:

ID 103609

ST. JUDE MEDICAL CRMD
15900 VALLEY VIEW CT
SYLMAR, CA 91392-9221

Equipment Location: 15900 VALLEY VIEW CT, SYLMAR, CA 91342

Equipment Description :

Ethylene Oxide Sterilizer, No. 2R, Getinge, Model No. GEE101420-1; 3' -3.4" W. x 4'-9.1" H x 6'-6.7" L., with a 100 KW Electric Steam Generator.

Conditions :

1. Operation of this equipment shall be conducted in accordance with all data and specifications submitted with the application under which this permit is issued unless otherwise noted below.
2. This equipment shall be properly maintained and kept in good operating condition at all times.
3. This equipment shall not be operated unless vented to the ETO control devices that are in compliance with SCAQMD Rule 1405 and have been issued a Permit to Construct or Operate by SCAQMD.
4. The total ethylene oxide (ETO) used in this facility shall not exceed 4,000 pounds in any one calendar year.
5. The total ethylene oxide (ETO) used in this facility shall not exceed 16 pounds in any one day.
6. A daily log indicating the date, the sterilization chamber identification number, the sterilization cycle start-up and completion time, the time of the day when the chamber is purged, and pounds of ETO used for each sterilization cycle shall be maintained for each ETO sterilization chamber.
7. The equipment and all the devices and components which are connected to this equipment shall be leak tested every six months using the latest CARB test method during conditions of maximum sterilant gas use.
8. There shall be no staging of sterilized products in uncontrolled areas of the plant. Any test or bio indicator removal shall be conducted in an enclosed location that is vented to an ETO control equipment.
9. The valves on ethylene oxide drums shall be completely closed when not in use. If closing of a drum valve cannot contain ETO, or if there is an indication of ETO leak from any other part of an ETO drum, the drum shall be immediately moved to area that is vented to an ETO control equipment.

PERMIT TO CONSTRUCT/OPERATE

10. The operator shall comply with all requirements specified in the Ethylene Oxide Airborne Toxic Control Measure (ATCM) for Sterilizers and Aerators, Parts 1 and 2 under Title 17 of California Code of Regulations, Sections 93108 and 93108.5 (17 CCR, Sections 93108 and 93108.5).

11. The operator shall comply with all requirements specified in the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations under Code of Federal Regulations, Title 40, Part 63 subpart O (40CFR 63, subpart O).

12. Materials processed in this equipment shall not contain any toxic air contaminants identified in Rule 1401, Table I, with an effective date of October 7, 2016 or earlier, except for ethylene oxide (CAS no. 75-21-8).

13. Records shall be maintained to demonstrate compliance with conditions 4, 5, 6, and 7. The records shall be kept for at least two years and made available to SCAQMD personnel upon request.

PERMIT TO CONSTRUCT/OPERATE

NOTICE

In accordance with Rule 206, this Permit to Operate or copy shall be posted on or within 8 meters of the equipment.

This permit does not authorize the emission of air contaminants in excess of those allowed by Division 26 of the Health and Safety Code of the State of California or the applicable Rules and Regulations of the South Coast Air Quality Management District (SCAQMD). This permit cannot be considered as permission to violate existing laws, ordinances, regulations or statutes of other government agencies.

Executive Officer

BY DORRIS M BAILEY/CW02

NSR DATA SUMMARY SHEET

Application No	594738
Application Type	10
Application status	PENDAPPRV
Previous Apps, Dev	,

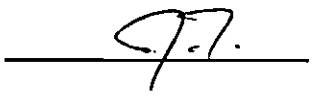
Company Name	ST. JUDE MEDICAL CRMD
Company ID	103609
Address	15900 VALLEY VIEW CT, SYLMAR, CA 91342-
Reclaim	NO
Reclaim Zone	01
Air Basin	SC
Zone	06
Title V	NO

Device ID	0 - ETHYLENE-OXIDE
Estimated Completion Date	12-31-2017
Heat Input Capacity	0 Millions BTU/Hr
Priority Reserve	NONE - No Priority Access Requested
Recommended Disposition	31 - PERMIT TO OPERATE GRANTED
PR Expiration	12-31-9999
School within 1,000 feet	NO
Operating Weeks per year	52
Operating Days per week	5
Operating Hours	
Monday	08:00 to 24:00
Tuesday	08:00 to 24:00
Wednesday	08:00 to 24:00
Thursday	08:00 to 24:00
Friday	08:00 to 24:00
Saturday	00:00 to 00:00
Sunday	00:00 to 00:00

Application No	594738	Company ID	103609

Emittant	ETHOXIDE	
BACT		
Cost effectiveness	NO	
Source Type	MINOR	
Emis Increase	0.000000000	
Modelling	N/A	
Public Notice	N	
Controlled Emission		
Max Hourly	0.000000000	Lbs/Hr
Max Daily	0.000000000	Lbs/day
Uncontrolled Emission		
Max Hourly	0.000000000	Lbs/Hr
Max Daily	0.000000000	Lbs/day
Current Emission		
BACT 30 Day Avg	0.000000000	Lbs/day
Annual Emission	0.000000000	Lbs/year
District Emission		

Emittant	ROG	
BACT		
Cost effectiveness	NO	
Source Type	MINOR	
Emis Increase	0	
Modelling	N/A	
Public Notice	N	
Controlled Emission		
Max Hourly	0.00	Lbs/Hr
Max Daily	0.00	Lbs/day
Uncontrolled Emission		
Max Hourly	0.00	Lbs/Hr
Max Daily	0.00	Lbs/day
Current Emission		
BACT 30 Day Avg	0.00	Lbs/day
Annual Emission	0.00	Lbs/year
District Emission		

Supervisor's Approval 

Supervisor's Review Date 9/8/17

Processed By carolynw

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT ENGINEERING AND COMPLIANCE APPLICATION PROCESSING AND CALCULATIONS	PAGE 1 OF 3 APPL. NO. 594738 PROCESSED BY CW02 CHECKED BY DATE 9-1-2017

EVALUATION REPORT FOR
PERMIT TO CONSTRUCT/OPERATE

APPLICANT'S NAME: St Jude Medical CRMD (Fac. ID 103609)

MAILING ADDRESS: 15900 Valley View Court
Sylmar, CA 91342

EQUIPMENT LOCATION: Same as above

EQUIPMENT DESCRIPTION:

Ethylene Oxide Sterilizer, No. 2R, Getinge, Model No. GEE101420-1; 3' -3.4" W. x 4'-9.1" H x 6'-6.7" L., with a 100 KW Electric Steam Generator.

HISTORY

St Jude Medical, operating under ID 103609, filed this application on June 6, 2017, to replace existing sterilizer G22027. This replacement of a sterilizer represents no impact on the current ETO sterilization operation since the usage limits and emissions will remain unchanged.

There are no compliance or violation notices issued to this facility,

PROCESS DESCRIPTION:

This facility is a medical device company that manufactures implantable defibrillators and pacemakers. To provide in-house sterilization service for all or part of its products, St Jude operates three ETO sterilizers that are vented to a catalytic oxidizer/abator (PO D87020). The sterilizers are equipped with electric steam generators to provide steam for maintaining proper humidity and temperature for the ETO chambers.

EMISSIONS CALCULATIONS:

The ETO sterilizing facility will continue to operate 16 hrs/day, 5 days/week, and 52 weeks/yr

There will be no change in ETO usage limit; 16 lb/day of total ETO facility usage limit (for all three sterilizers), and 4000 lbs/yr of total ETO facility usage limit (for all three sterilizers).

With 99.9% control efficiency by the oxidizer, controlled emissions would be 0.016 lb/day of ETO from all three units.

R1 = lb/hr of ROG; R2 = 0.001 lb/hr of ROG
R1 = lb/hr of ETO; R2 =0 .001 lb/hr of ETO

The controlled and uncontrolled emissions for this facility is "bubbled" under Sterilizer 3R (G37118).

RULES EVALUATION:

Rule 212: **Standards for Approving Permits and Issuing Public Notice:** There will be no emission increase for this application. The rule does not apply.

Rule 401: **Visible Emissions:** The opacity limits set forth in Rule 401 are not expected to be exceeded. This facility is expected to comply with Rule 401.

REG XIII: **New Source Review:**

1301 General: There will be no emission increase for this application. This rule does not apply.

1313(e) Permit Conditions: Condition 2 requires facility to maintain and keep equipment in good operating condition.

1313(g) Emission Limitation Permit Conditions

(1) Identified BACT condition: BACT for this equipment is a catalytic oxidizer permitted under D87020. Condition #3 requires this equipment be vented to a control device that complies with 1405 and is permitted.

(2) Daily maximum emissions: Condition #5 limits facility wide ETO usage to 16 pounds per day.

Rule 1401: **New Source Review of Toxic Air Contaminants:** This is a functionally identical replacement with no change in operation or ETO usage. Therefore, no increase in emissions is expected from this equipment. Continued compliance with this rule is expected

Rule 1405: **Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes:** This new permit will not have any emission increase as it is a replacement of an existing unit. Previous source testing results have demonstrated compliance with the rule requirements. Continued compliance with this rule is expected.

CONCLUSIONS & RECOMMENDATIONS:

This application is expected to comply with all applicable District Rules and Regulations. A Permit to Construct/Operate is recommended subject to the following conditions:

PERMIT CONDITIONS:

1. Operation of this equipment shall be in compliance with all data and specifications submitted with the application under which this permit was issued, unless otherwise noted below.

2. This equipment shall be properly maintained and kept in good operating condition at all times.

3. This equipment shall not be operated unless vented to the ETO control devices that are in compliance with SCAQMD Rule 1405 and have been issued a Permit to Construct or Operate by SCAQMD.

4. The total ethylene oxide (ETO) used in this facility shall not exceed 4,000 pounds in any one calendar year.

5. The total ethylene oxide (ETO) used in this facility shall not exceed 16 pounds in any one day.

6. A daily log indicating the date, the sterilization chamber identification number, the sterilization cycle start-up and completion time, the time of the day when the chamber is purged, and pounds of ETO used for each sterilization cycle shall be maintained for each ETO sterilization chamber.

7. The equipment and all the devices and components which are connected to this equipment shall be leak tested every six months using the latest CARB test method during conditions of maximum sterilant gas use.

8. There shall be no staging of sterilized products in uncontrolled areas of the plant. Any test or bio indicator removal shall be conducted in an enclosed location that is vented to an ETO control equipment.

9. The valves on ethylene oxide drums shall be completely closed when not in use. If closing of a drum valve cannot contain ETO, or if there is an indication of ETO leak from any other part of an ETO drum, the drum shall be immediately moved to area that is vented to an ETO control equipment.

10. The operator shall comply with all requirements specified in the Ethylene Oxide Airborne Toxic Control Measure (ATCM) for Sterilizers and Aerators, Parts 1 and 2 under Title 17 of California Code of Regulations, Sections 93108 and 93108.5 (17 CCR, Sections 93108 and 93108.5).

11. The operator shall comply with all requirements specified in the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations under Code of Federal Regulations, Title 40, Part 63 subpart O (40CFR 63, subpart O).

12 Add 1401 condition with an effective date of Oct 7, 2016.

13. Records shall be maintained to demonstrate compliance with conditions 4, 5, 6, and 7. The records shall be kept for at least two years and made available to SCAQMD personnel upon request.

APPENDIX B - FIGURES

Prepared By: Trinity Consultants

ST. JUDE MEDICAL

St. Jude Medical, Inc.
15900 Valley View Court
Sylmar, CA 91342

Description: **Vicinity Map - Sterilizer Replacement Location**

Scale	Date	Figure
1"=~747'	05/15/2017	1

Prepared By: Trinity Consultants

ST. JUDE MEDICAL

St. Jude Medical, Inc.
15900 Valley View Court
Sylmar, CA 91342

Description: **Site Map - Sterilizer Replacement Location**

Scale	Date	Figure
1"=~194'	05/15/2017	2

APPENDIX C - STERILIZER SYSTEM SPECIFICATIONS

GETINGE
GETINGE GROUP

Proposal For :	Prepared By:
St. Jude Medical Ed Reyes Sylmar CA	M Hill / Bill Scholl Getinge 1777 East Henrietta Road Rochester NY 14623
	Quote Number:Q-080399 Rev 7 **Last Modified Date:** 12/01/2016 **Print Date:** 12/01/2016

Quotation

GETINGE EO STERILIZER SYSTEM

Costumer:	ST. JUDE MEDICAL
Contacts:	Ed Reyes
Getinge:	Don Seitz / Bill Scholl / Mark Hill
Quote ref:	Q-0808399 Rev 7
Delivery:	Approx. 8 months (Ex-works)
Date:	1st December 2016
References:	1. St Jude URS Rev B 2. Getinge URR-080399 Rev 2 3.

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1. EQUIPMENT DETAILS & SCOPE OF DELIVERY

1.1 Getinge GEE Ethylene Oxide Gas Sterilizer

Type	GEE101420-1 (right sliding door)
Qty	1
Producer	Getinge
Sterilizer	GEE101420-1 Getinge's ethylene oxide sterilizers are fully automatic with operator cycles for use with 100% EO gas to sterilizer medical devices at low temperatures in a sub atmospheric cycle profile.

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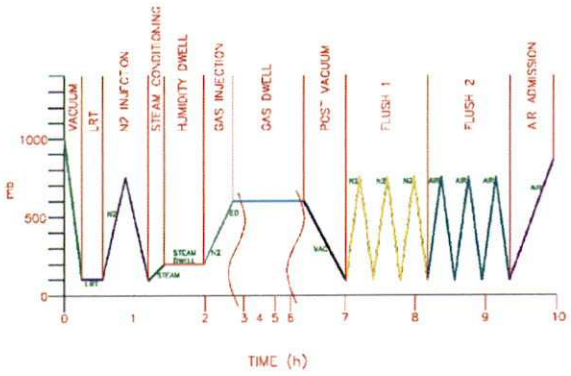


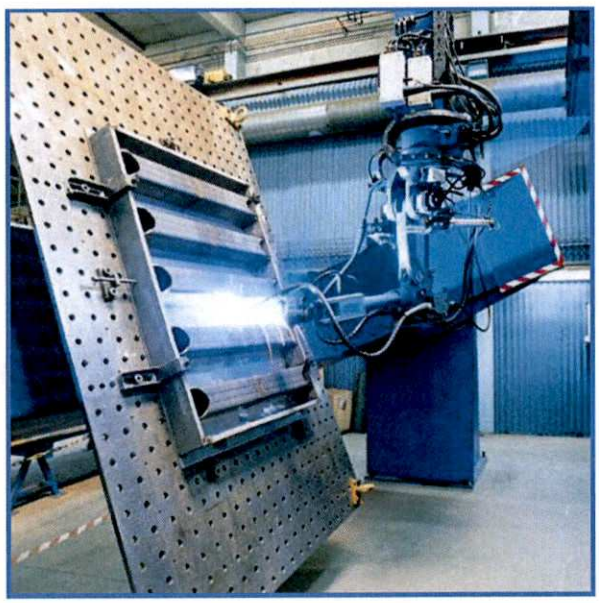
Size

Internal chamber size (dimensions exclude internal baffle size) 1000mm W x 1450mm H x 2000mm D. Internal baffles included.

Chamber

Sterilizer chamber is made form 304 grade stainless steel and is finished with a bead blast result internally.

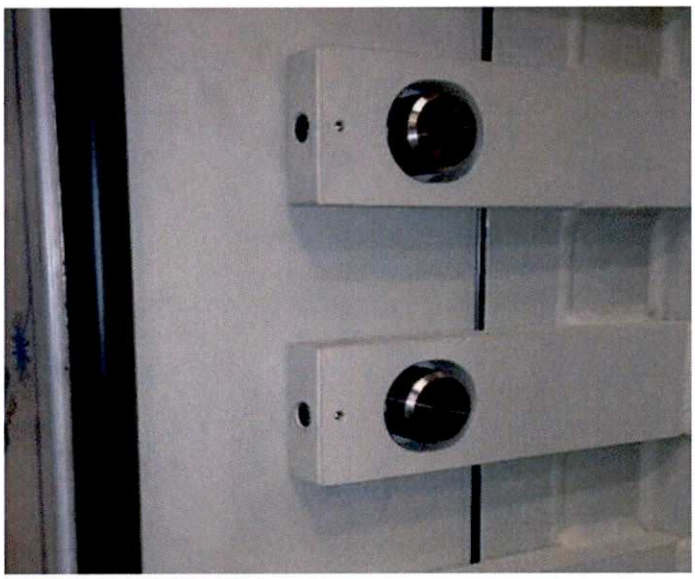
Auto welding machines provide a high quality construction of chamber and eliminate imperfections normally associated with a manual welding procedure *(large door being welded below).*



The chamber is jacketed with U section channels which provide the strength in the construction and also are used to channel the heating water to maintain the process condition at sterilizing temperature *(U section shown below).*

Doors

The unit is single door design with a load and unload door at each end which are fully automatic in operation and powered by a pneumatic bi direction motor with a leading edge which acts as a safety device to stop the door when it meets an obstruction. The door is retained by engaging pins into holes on each edge of the door *(shown on the photo below which also shows the black bump safety strip).*



Doors slide horizontally to open and close, the motor drives the door which is hung from a steel beam and linear bearings move along a smooth stainless steel bar *(see below).*

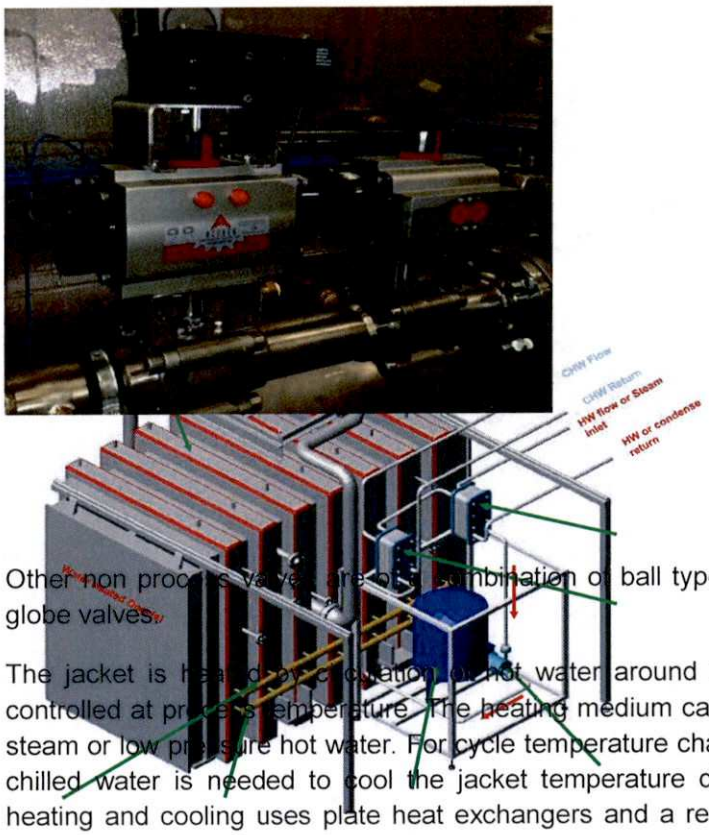
Piping

The steam, EO, gas lines, re-circulation system and gas exhaust piping are manufactured from stainless steel, welded in place as much as practical to avoid potential leak points. Liquid EO lines are piped in schedule 40 pipe and all other stainless steel is in schedule 10 *(shown below.*

The non process side which is mainly the jacket heating and cooling circuits / manifold are in stainless steel as per sterilizer #3.

Valves

Process valves are weld in place ball type with a pneumatic actuator, these are as standard anti-static fire safe type. Critical valves are duplex and also have a switch box fitted to provide a position feedback signal to the PLC / SCADA.



Other non process valves are of a combination of ball type or piston globe valves.

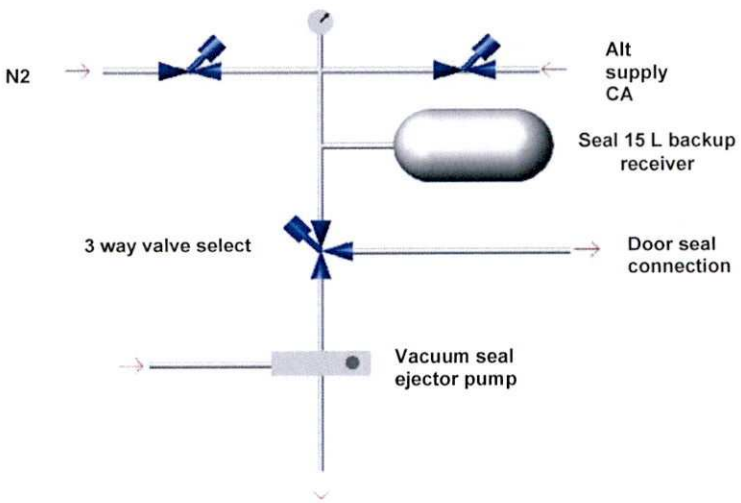
Jacket heating

The jacket is heated by circulation of hot water around it which is controlled at process temperature. The heating medium can either by steam or low pressure hot water. For cycle temperature changes then chilled water is needed to cool the jacket temperature down. Both heating and cooling uses plate heat exchangers and a re-circulation pump to give a good even temperature in the system *(see example pipe skid below)*.

The door of the sterilizer, re-circulation blower manifold and EO pipe from the chamber to the gas dispense room are all heated to the process temperature by the jacket water circuit *(actual skid below).*

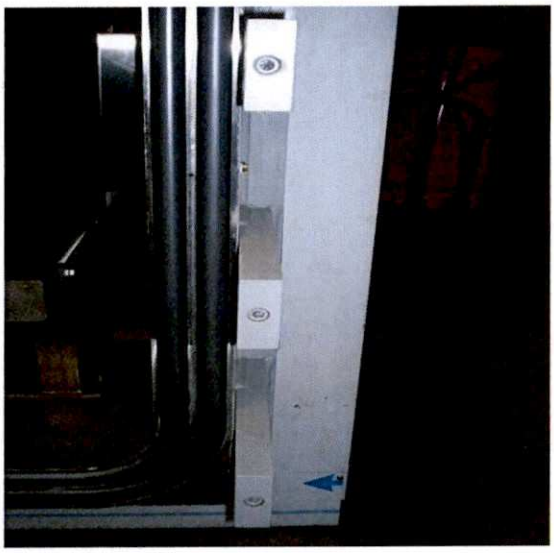
Door sealing

All Getinge GEE EO sterilizers have dual door seal on the door which is based on two O rings of 28mm diameter. Seals are pushed onto the inner door face by pressurized nitrogen and retracted into their groove using vacuum. The is a high pressure reservoir of nitrogen which will maintain the seal should there by a power failure. And if nitrogen is lost during the cycle there is backup from compressed air *(see diagram below).*



Between each seal is a monitoring area which a pressure sensor is connect into the gap. This is a safety device that monitors for pressure

increase or decrease and reporting on door seal failure to the PLC / SCADA *(twin seal below).*

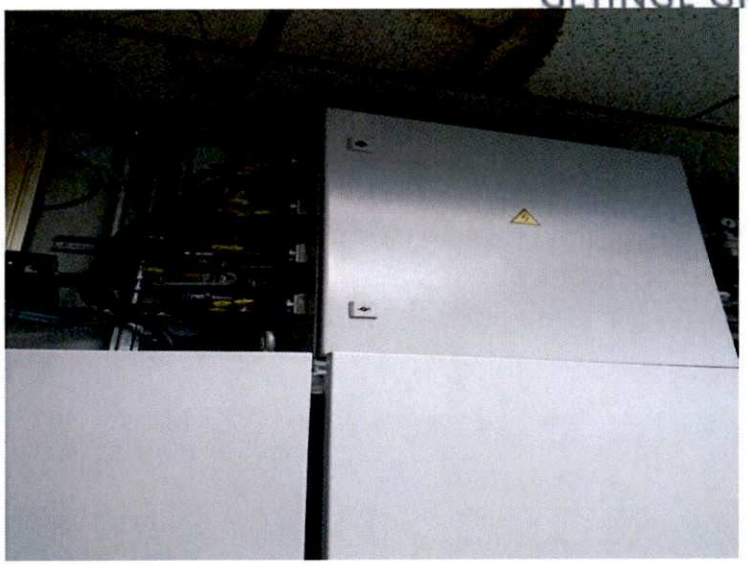


Filter

All media coming into the chamber enters via the re-circulation line to have an immediate mixing effect. A filter is included for the media entry which is 0.2 micron rated.

Control system

The control platform is based around a AB PLC which is housed in a free standing cabinet and located in the safe area (non Zoned). There are two cabinets, one for the high voltage items (contactors, transformers etc) and the second has the control PLC, safety barriers and other low voltage items. 24V solenoid valves are located in a separate box attached to the main cabinet, on top. Air lines come from this box come out to the left side (see photo below). Solenoid valves to send pneumatic pilot signals to the equipment process ball or piston valves



The PLC type is a AB Logix series with Ethernet port for exporting of data to the supervisor system (supplied by others). It is supplied complete with a colour laser A4 printer for batch process printing.

Sensors

Sensors are supplied are duplex where requested for use with the monitoring system, here the additional sensors would be wired to a terminal block for connection by others.

In addition to the standard sensors there was be humidity and gas concentration sensors are fitted to enable parametric release when needed (2 dual DIR element Gas concentration and 2 RH single sensors are included).

SCADA

Each line will be fitted with a dedicated SCADA PC station which is remote located in the control room. The SCADA is based in the InTouch Wonderware system which is installed into each PC. The package is complete with CFR21 Pt11 compliance system for audit trail and storage of encrypted PDF cycle logs in an SQL database, complete with Getinge certificate of compliance as per sterilizer #3.

The SCADA has many screens to drive the plant and monitor the equipment, some examples are :-

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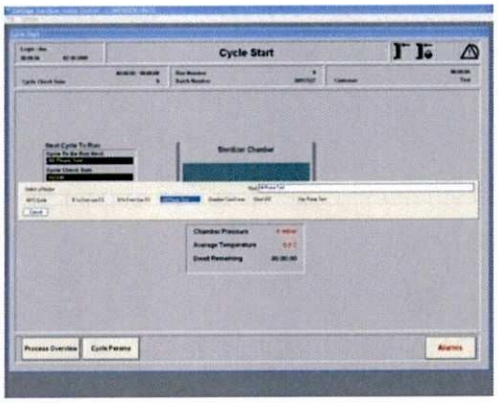
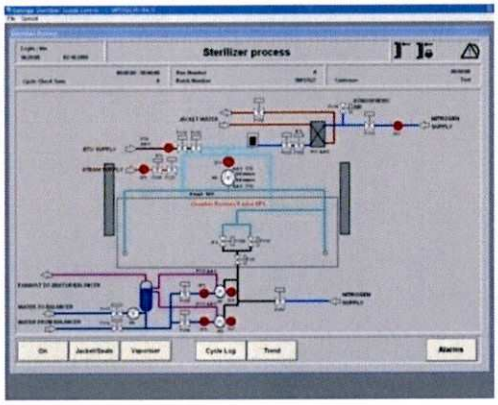
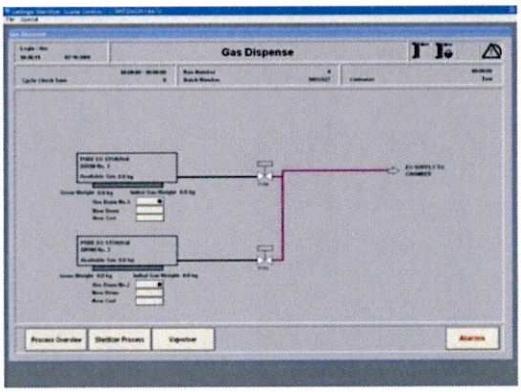


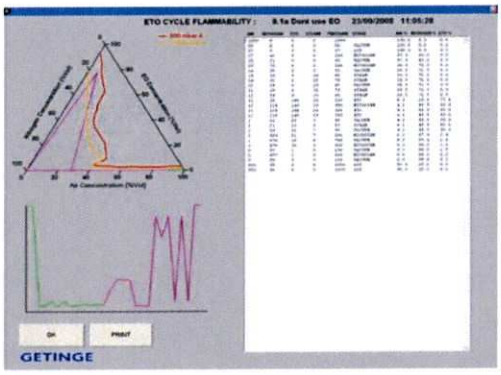
Cycle Start Screen



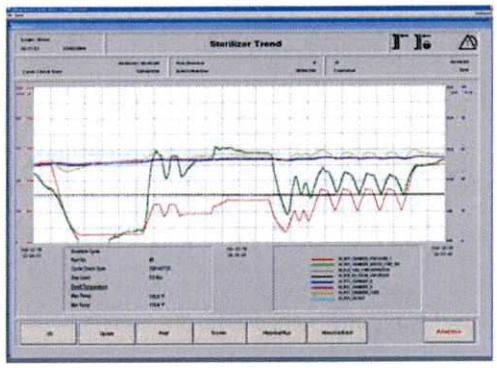
GEE Overview Screen



Gas Room



Flammability Curve



Flammability Curve

Batch Report

The SCADA system will store all batch data and or export this to another system.

Process records can be printed in full or as a summary sheet. If parametric release is to be utilized then the go no go parameters are setup in the SCADA and when the process is within these limits the text remains in black, if outside the text turns red at the point in the cycle where the cycle is out of specification *(example chart below)*.

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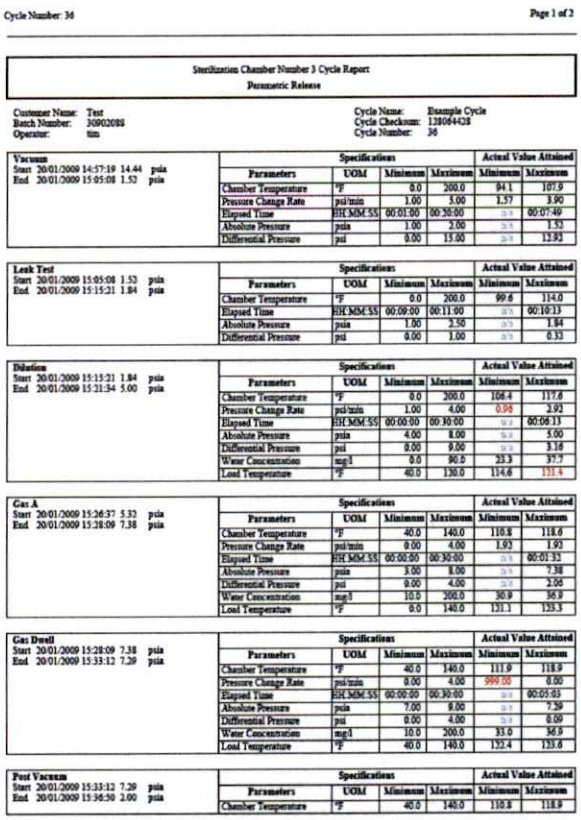


Cycle Number: 36 Page 1 of 2

Sterilization Chamber Number 3 Cycle Report
Parametric Release

Customer Name: Test
Batch Number: 36902088
Operator: tim

Cycle Name: Example Cycle
Cycle Checksum: 13864428
Cycle Number: 36

Vacuum			Specifications		Actual Value Attained	
Start 20/01/2009 14:57:19 14.44 psia	Parameters	UOM	Minimum	Maximum	Minimum	Maximum
End 20/01/2009 15:05:08 1.52 psia	Chamber Temperature	°F	0.0	200.0	94.1	107.9
	Pressure Change Rate	psi/min	1.00	5.00	1.57	3.90
	Elapsed Time	HH:MM:SS	00:01:00	00:20:00	n/a	00:07:49
	Absolute Pressure	psia	1.00	2.00	n/a	1.52
	Differential Pressure	psi	0.00	15.00	n/a	12.92

Leak Test			Specifications		Actual Value Attained	
Start 20/01/2009 15:05:08 1.52 psia	Parameters	UOM	Minimum	Maximum	Minimum	Maximum
End 20/01/2009 15:15:21 1.84 psia	Chamber Temperature	°F	0.0	200.0	99.6	114.0
	Elapsed Time	HH:MM:SS	00:09:00	00:11:00	n/a	00:10:13
	Absolute Pressure	psia	1.00	2.50	n/a	1.84
	Differential Pressure	psi	0.00	1.00	n/a	0.32

Dilution			Specifications		Actual Value Attained	
Start 20/01/2009 15:15:21 1.84 psia	Parameters	UOM	Minimum	Maximum	Minimum	Maximum
End 20/01/2009 15:21:34 5.00 psia	Chamber Temperature	°F	0.0	200.0	108.4	117.6
	Pressure Change Rate	psi/min	1.00	4.00	0.96	2.92
	Elapsed Time	HH:MM:SS	00:00:00	00:30:00	n/a	00:06:13
	Absolute Pressure	psia	4.00	8.00	n/a	5.00
	Differential Pressure	psi	0.00	9.00	n/a	3.16
	Water Concentration	mg/l	0.0	90.0	23.3	37.7
	Load Temperature	°F	40.0	130.0	114.6	121.4

Gas A			Specifications		Actual Value Attained	
Start 20/01/2009 15:26:37 5.32 psia	Parameters	UOM	Minimum	Maximum	Minimum	Maximum
End 20/01/2009 15:28:09 7.38 psia	Chamber Temperature	°F	40.0	140.0	110.8	118.6
	Pressure Change Rate	psi/min	0.00	4.00	1.93	1.93
	Elapsed Time	HH:MM:SS	00:02:00	00:30:00	n/a	00:01:32
	Absolute Pressure	psia	3.00	8.00	n/a	7.38
	Differential Pressure	psi	0.00	4.00	n/a	2.06
	Water Concentration	mg/l	10.0	200.0	30.9	36.9
	Load Temperature	°F	0.0	140.0	121.1	123.3

Gas Dwell			Specifications		Actual Value Attained	
Start 20/01/2009 15:28:09 7.38 psia	Parameters	UOM	Minimum	Maximum	Minimum	Maximum
End 20/01/2009 15:33:12 7.29 psia	Chamber Temperature	°F	40.0	140.0	111.9	118.9
	Pressure Change Rate	psi/min	0.00	4.00	999.00	0.00
	Elapsed Time	HH:MM:SS	00:00:00	00:30:00	n/a	00:05:03
	Absolute Pressure	psia	7.00	8.00	n/a	7.29
	Differential Pressure	psi	0.00	4.00	n/a	0.09
	Water Concentration	mg/l	10.0	200.0	33.0	36.9
	Load Temperature	°F	40.0	140.0	122.4	123.6

Post Vacuum			Specifications		Actual Value Attained	
Start 20/01/2009 15:33:12 7.29 psia	Parameters	UOM	Minimum	Maximum	Minimum	Maximum
End 20/01/2009 15:36:50 2.00 psia	Chamber Temperature	°F	40.0	140.0	110.8	118.9

Re-circ. System

The chamber re-circulation system is based on an external fan directing the atmosphere inside the chamber via internal baffles mounted on each side of the chamber and on the roof between the two pallet lines. Fan is mounted at floor level.

Based on an ATEX Cat II rated Halifax fan the system circulates 10 chamber volumes / hour (to guarantee URS performance).

The fan unit is complete with inlet and outlet flame arresters and also has other in-built safety devices which are sent to the PLC for monitoring, these include – flame detection sensor, level monitor for mechanical seal, dual bearings with vibration sensors, spark proof fan housing and temperature sensor.

The re-circulation piping is in stainless steel and is sleeved with a stainless steel jacket and heated with the jacket water circuit to keep the re-circulation gas at temperature *(shows a top mounted fan).*

Vacuum pump

Each chamber has a dedicated liquid ring vacuum pump with internal wetted surfaces from stainless steel.

The pump's sealing water is closed loop and fed cooled by chilled water to get the maximum vacuum rates.

This sealing water is on a closed loop system between the vacuum pump and the pump separator.

Gas room

A single bottle & scale supplies gas to all three sterilizers. Gas is vaporized locally next to the sterilizer.

ATEX

The sterilizer assembly will be delivered fully in accordance with the ATEX directive (94/9/EC). BSI is used as our notified body to inspect the sterilizers and to issue a declaration of conformity as shown on the below.

GETINGE

EC DECLARATION OF CONFORMITY
ATEX Directive
94/9/EC

Manufacturer:	GETINGE UK LTD. Orchard Way Calladine Park Sutton-in-Ashfield Nottinghamshire NG17 1JU United Kingdom
Product description:	GEE 1429108-AR2 ETO Sterilizer Assembly (supplied without control system), Robotised Transport System (RATS) & Associated Gas Room Equipment
Product serial number:	175201
Year of manufacture:	2006

Conformity assessment module:	Annex IX Unit Verification
As approved by:	Notified Body No: 0086 BSI Product Services Maylands Avenue Hemel Hempstead Herts HP2 4SQ UK
Notified body certificate:	BSI 06 ATEX 507749X

Standards applied in full or in part:	EN 1127-1 EN 13463-1 EN 60079-14:2003
Other relevant EU Directives:	Machinery Directive 98/37/EC Low Voltage Directive 73/23/EEC Electromagnetic Compatibility Directive 89/336/EEC and amendment 92/31/EEC Pressure Equipment Directive 97/23/EC
Authorised signatory:	

Quality Assurance Manager John Noble 29 June 2006

1.2 Removal of Existing Sterilizer

Removal & Disposal of old chamber

1.3 Scope of Site Works

Uncrating of new equipment

Set & level seismic anchors

Assembly of New Equipment

Electrical (no core drilling)

- Install electrical and pneumatic raceways in equipment room.
- Pull wires from control cabinet and solenoid cabinet to equipment room, through conduits and placed on raceways.
- Pull control wires for PC, printer and scale display from cabinet room to control room, through conduit.
- Complete interconnections to include
    - Connection to electrical cabinet (including PLC cabinet) in control room (power and control)
    - Connections to solenoid cabinet in control room (control)
    - Connections to all motors (power and control)
    - Connections to sterilizer and panel in containment room (control)
    - Connection to CSG (control)
    - Connections to vaporizer (control)
    - Connection to scale an display (control)
    - Connection to PC and display in PC room (control)
    - Final connections to include (5 feet max distance between utility connection and equipment connection)
    - Main power to electrical cabinet
    - Main power to control room PC and printer

Mechanical (no core drilling)

- Install raceways for compressed air in equipment room
- Install clean steam line form the CSG room to equipment room within 5 feet of CSG and equipment
- Compressed air lines to solenoid cabinet.
- Compressed air lines to sterilizer valves.
- Compressed air lines to jacket heating valves.
- Compressed air lines to re-circulation fan valves.
- Compressed air lines to CSG valves.
- Compressed air lines between sterilizer, vacuum pump skid, and jacket heating skid.
- Compressed air lines to vaporizer valves.
- Vacuum pump skid pipe and valve assembly.
- Re-circulating pump skid pipe and valve assembly.
- Jacket heating skid pipe and valve assembly.
- Sterilizer pipe and valve assembly.
- CSG skid pipe and valve assembly.
- Clean steam connection to sterilizer from CSG.
- Nitrogen line connection from vaporizer to sterilizer.
- EO gas line from vaporizer to sterilizer.

- Facility water lines from jacket heating skid to sterilizer and back to jacket heating skid.
- Chilled water lines between all heat exchangers
- Air lines from recirculation fan skid to sterilizer and back to recirculation fan skid.

Final connections to include (5 feet max distance between facility utility connection and equipment connection)

- From existing Facility water line connection to sterilizer.
- From existing facility plant steam line connection to sterilizer.
- From condensate return line heat exchanger connection on sterilizer to existing drain.
- From existing compressed air line connection to sterilizer.
- From exhaust connection on the sterilizer to existing catalytic oxidizer line connection.
- From existing water line connection to vacuum pump.
- From vacuum pump water separator tank to existing drain.
- From existing chilled water supply line connection to sterilizer.
- From sterilizer chilled water return line connection to existing chilled water return connection.
- From safety valve outlet to existing exhaust line.
- From existing plant steam line connection to CSG.
- From condensate return line on CSG to existing blow down tank line.
- From existing compressed air line connection to CSG.
- From existing feed water line connection to CSG.
- From existing compressed air line connection to Solenoid cabinet.
- From existing Nitrogen line connection to vaporizer.
- From existing plant steam line connection to vaporizer.
- From drain line connection on vaporizer to existing drain.

Panel Trim Work to include 1 – 3 day.

1.4 SAT and IQ/OQ

Commissioning, SAT and IQ/OQ would be done in accordance with the URS and on Getinge's protocol sheets. Our experience engineers would conduct this process.

For this work we would require that all services are fully operational while we are on site.

On completion the test reports would be presented in binders at the same time of the O+M manuals.

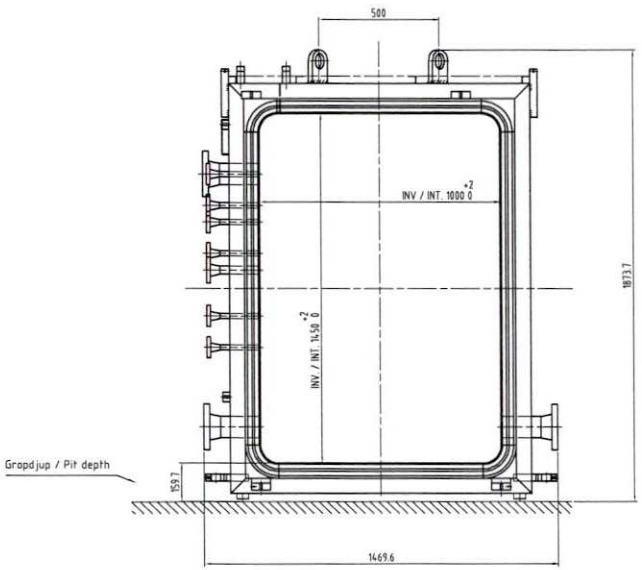
1.5 Site Training

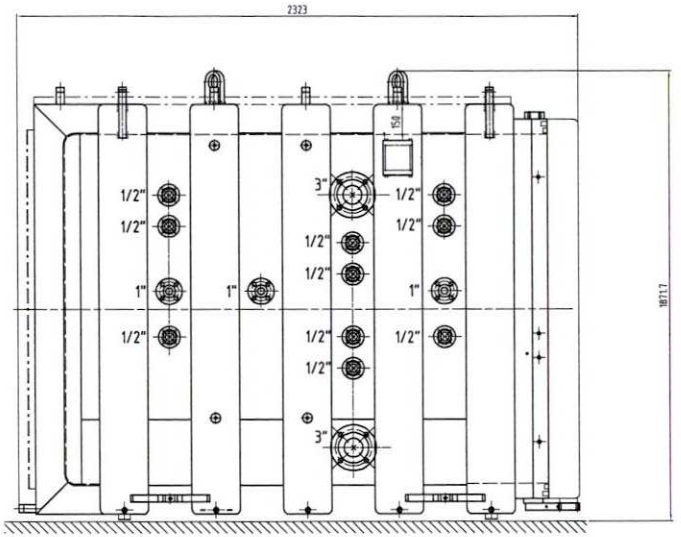
Site training would be conducted at the end of each SAT and then formally at the end of the project. Experience staff would provide certified Getinge training in line with our own Getinge Academy.

1 day are included in the scope.

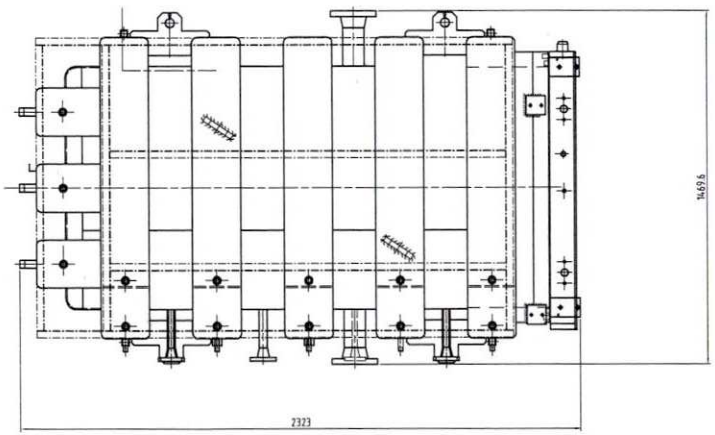
Topics covered are :-

- Principals of EO sterilization
- SCADA operation
- Safety system and awareness of EO gas
- Daily, weekly and monthly maintenance checks
- Loading system correct operation





Weight : 1550 Kg (Total incl.doors ca 1850 kg)



APPENDIX D - SCAQMD OPERATING PERMITS

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT
21865 Copley Drive, Diamond Bar, CA 91765

PERMIT TO OPERATE

Permit No.
G22028
A/N 543771

This initial permit must be renewed ANNUALLY unless the equipment is moved, or changes ownership.
If the billing for the annual renewal fee (Rule 301.f) is not received by the expiration date, contact the District.

ID 103609

Legal Owner
or Operator:

ST. JUDE MEDICAL CRMD
15900 VALLEY VIEW CT
SYLMAR, CA 91392-9221

Equipment Location: 15900 VALLEY VIEW CT, SYLMAR, CA 91342

Equipment Description :

ETHYLENE OXIDE STERILIZER NO. 1, GETINGE, MODEL NO. 8440AR1, 2'-11"W. X 4'-9" H. X 5'-0" L., WITH A 100 KW ELECTRIC STEAM GENERATOR.

Conditions :

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.

2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.

3. THIS EQUIPMENT SHALL NOT BE OPERATED UNLESS IT IS VENTED TO THE ETO CONTROL DEVICES THAT ARE IN COMPLIANCE WITH THE AQMD RULE 1405 AND HAVE BEEN ISSUED PERMIT TO CONSTRUCT OR OPERATE BY THE AQMD.

4. THE TOTAL ETHYLENE OXIDE (ETO) USED IN THIS FACILITY SHALL NOT EXCEED 4,000 POUNDS IN ANY ONE CALENDAR YEAR.

5. THE TOTAL ETHYLENE OXIDE (ETO) USED IN THIS FACILITY SHALL NOT EXCEED 16 POUNDS IN ANY ONE DAY.

6. A DAILY LOG INDICATING THE DATE, THE STERILIZATION CHAMBER IDENTIFICATION NUMBER, THE STERILIZATION CYCLE START-UP AND COMPLETION TIME, THE TIME OF THE DAY WHEN THE CHAMBER IS PURGED, AND POUNDS OF ETO USED FOR EACH STERILIZATION CYCLE SHALL BE MAINTAINED FOR EACH ETO STERILIZATION CHAMBER.

7. THIS EQUIPMENT AND ALL THE DEVICES AND COMPONENTS WHICH ARE CONNECTED TO THIS EQUIPMENT SHALL BE LEAK TESTED EVERY SIX MONTH USING THE LATEST CARB TEST METHOD DURING CONDITIONS OF MAXIMUM STERILANT GAS USE.

8. THERE SHALL BE NO STAGING OF STERILIZED PRODUCTS IN UNCONTROLLED AREAS OF THE PLANT. ANY TEST OR BIO INDICATOR REMOVAL SHALL BE CONDUCTED IN AN ENCLOSED LOCATION THAT IS VENTED TO AN ETO CONTROL EQUIPMENT.

ORIGINAL

PERMIT TO OPERATE

9. THE VALVES ON ETHYLENE OXIDE DRUMS SHALL BE COMPLETELY CLOSED WHEN NOT IN USE. IF CLOSING OF A DRUM VALVE CANNOT CONTAIN ETO, OR IF THERE IS AN INDICATION OF ETO LEAK FROM ANY OTHER PART OF AN ETO DRUM, THE DRUM SHALL BE IMMEDIATELY MOVED TO AREA THAT IS VENTED TO AN ETO CONTROL EQUIPMENT.

10. THE OPERATOR SHALL COMPLY WITH ALL REQUIREMENTS SPECIFIED IN THE ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE (ATCM) FOR STERILIZERS AND AERATORS, PARTS 1 AND 2 UNDER TITLE 17 OF CALIFORNIA CODE OF REGULATIONS, SECTIONS 93108 AND 93108.5 (17 CCR, SECTIONS 93108 AND 93108.5).

11. THE OPERATOR SHALL COMPLY WITH ALL REQUIREMENTS SPECIFIED IN THE NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAP) FOR ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS UNDER CODE OF FEDERAL REGULATIONS, TITLE 40, PART 63 SUBPART O (40 CFR 63, SUBPART O).

12. RECORDS SHALL BE MAINTAINED TO DEMONSTRATE COMPLIANCE WITH CONDITIONS 4, 5, 6 AND 7. THE RECORDS SHALL BE KEPT FOR AT LEAST TWO YEARS AND MADE AVAILABLE TO AQMD PERSONNEL UPON REQUEST.

NOTICE

IN ACCORDANCE WITH RULE 206, THIS PERMIT TO OPERATE OR COPY SHALL BE POSTED ON OR WITHIN 8 METERS OF THE EQUIPMENT.

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EXECUTIVE OFFICER

Dorris M Bailey

By Dorris M.Bailey/JY02
12/13/2012

ORIGINAL

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT
21865 Copley Drive, Diamond Bar, CA 91765

PERMIT TO OPERATE

Permit No.
G22027
A/N 543770

This initial permit must be renewed ANNUALLY unless the equipment is moved, or changes ownership.
If the billing for the annual renewal fee (Rule 301.f) is not received by the expiration date, contact the District.

ID 103609

Legal Owner
or Operator: ST. JUDE MEDICAL CRMD
15900 VALLEY VIEW CT
SYLMAR, CA 91392-9221

Equipment Location: 15900 VALLEY VIEW CT, SYLMAR, CA 91342

Equipment Description :

ETHYLENE OXIDE STERILIZER NO. 2, GETINGE, MODEL NO. 8440AR1, 2'-2"W. X 3'-0" H. X 5'-0" L., WITH A 100 KW ELECTRIC STEAM GENERATOR.

Conditions :

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.

2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.

3. THIS EQUIPMENT SHALL NOT BE OPERATED UNLESS IT IS VENTED TO THE ETO CONTROL DEVICES THAT ARE IN COMPLIANCE WITH THE AQMD RULE 1405 AND HAVE BEEN ISSUED PERMIT TO CONSTRUCT OR OPERATE BY THE AQMD.

4. THE TOTAL ETHYLENE OXIDE (ETO) USED IN THIS FACILITY SHALL NOT EXCEED 4,000 POUNDS IN ANY ONE CALENDAR YEAR.

5. THE TOTAL ETHYLENE OXIDE (ETO) USED IN THIS FACILITY SHALL NOT EXCEED 16 POUNDS IN ANY ONE DAY.

6. A DAILY LOG INDICATING THE DATE, THE STERILIZATION CHAMBER IDENTIFICATION NUMBER, THE STERILIZATION CYCLE START-UP AND COMPLETION TIME, THE TIME OF THE DAY WHEN THE CHAMBER IS PURGED, AND POUNDS OF ETO USED FOR EACH STERILIZATION CYCLE SHALL BE MAINTAINED FOR EACH ETO STERILIZATION CHAMBER.

7. THIS EQUIPMENT AND ALL THE DEVICES AND COMPONENTS WHICH ARE CONNECTED TO THIS EQUIPMENT SHALL BE LEAK TESTED EVERY SIX MONTH USING THE LATEST CARB TEST METHOD DURING CONDITIONS OF MAXIMUM STERILANT GAS USE.

8. THERE SHALL BE NO STAGING OF STERILIZED PRODUCTS IN UNCONTROLLED AREAS OF THE PLANT. ANY TEST OR BIO INDICATOR REMOVAL SHALL BE CONDUCTED IN AN ENCLOSED LOCATION THAT IS VENTED TO AN ETO CONTROL EQUIPMENT.

ORIGINAL

9. THE VALVES ON ETHYLENE OXIDE DRUMS SHALL BE COMPLETELY CLOSED WHEN NOT IN USE. IF CLOSING OF A DRUM VALVE CANNOT CONTAIN ETO, OR IF THERE IS AN INDICATION OF ETO LEAK FROM ANY OTHER PART OF AN ETO DRUM, THE DRUM SHALL BE IMMEDIATELY MOVED TO AREA THAT IS VENTED TO AN ETO CONTROL EQUIPMENT.

10. THE OPERATOR SHALL COMPLY WITH ALL REQUIREMENTS SPECIFIED IN THE ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE (ATCM) FOR STERILIZERS AND AERATORS, PARTS 1 AND 2 UNDER TITLE 17 OF CALIFORNIA CODE OF REGULATIONS, SECTIONS 93108 AND 93108.5 (17 CCR, SECTIONS 93108 AND 93108.5).

11. THE OPERATOR SHALL COMPLY WITH ALL REQUIREMENTS SPECIFIED IN THE NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAP) FOR ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS UNDER CODE OF FEDERAL REGULATIONS, TITLE 40, PART 63 SUBPART O (40 CFR 63, SUBPART O).

12. RECORDS SHALL BE MAINTAINED TO DEMONSTRATE COMPLIANCE WITH CONDITIONS 4, 5, 6 AND 7. THE RECORDS SHALL BE KEPT FOR AT LEAST TWO YEARS AND MADE AVAILABLE TO AQMD PERSONNEL UPON REQUEST.

NOTICE

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EXECUTIVE OFFICER

Dorris M Bailey

By Dorris M.Bailey/JY02
12/13/2012

ORIGINAL

South Coast Air Quality Management District
21865 Copley Drive, Diamond Bar, CA 91765-4178

PERMIT TO CONSTRUCT/OPERATE

Permit No.
G37118
A/N 576947

This initial permit must be renewed ANNUALLY unless the equipment is moved, or changes ownership.
If the billing for the annual renewal fee (Rule 301.f) is not received by the expiration date, contact the District.

ID 103609

Legal Owner or Operator:
ST. JUDE MEDICAL CRMD
15900 VALLEY VIEW CT
SYLMAR, CA 91392-9221

Equipment Location: 15900 VALLEY VIEW CT, SYLMAR, CA 91342

Equipment Description :

Ethylene Oxide Sterilizer No. 3R, Getinge, Model No. GE1014-AR1, 3'-3.4" W. x 4'-9.1" H. x 6'-6.7" L., with a 100 kw Electric Steam Generator

Conditions :

1. Operation of this equipment shall be conducted in accordance with all data and specifications submitted with the application under which this permit is issued unless otherwise noted below.
2. This equipment shall be properly maintained and kept in good operating condition at all times.
3. This equipment shall not be operated unless it is vented to the ETO control devices that are in compliance with the AQMD rule 1405 and have been issued Permit to Construct or Operate by the AQMD.
4. The total ethylene oxide (ETO) used in this facility shall not exceed 4,000 pounds in any one calendar year.
5. The total ethylene oxide (ETO) used in this facility shall not exceed 16 pounds in any one day.
6. A daily log indicating the date, the sterilization chamber identification number, the sterilization cycle start-up and completion time, the time of the day when the chamber is purged, and pounds of ETO used for each sterilization cycle shall be maintained for each ETO sterilization chamber.
7. This equipment and all the devices and components which are connected to this equipment shall be leak tested every six month using the latest CARB test method during conditions of maximum sterilant gas use.
8. There shall be no staging of sterilized products in uncontrolled areas of the plant. Any test or bio indicator removal shall be conducted in an enclosed location that is vented to an ETO control equipment.
9. The valves on ethylene oxide drums shall be completely closed when not in use. If closing of a drum valve cannot contain ETO, or if there is an indication of ETO leak from any other part of an ETO drum, the drum shall be immediately moved to area that is vented to an ETO control equipment.

ORIGINAL

10. The operator shall comply with all requirements specified in the Ethylene Oxide Airborne Toxic Control Measure (ATCM) for sterilizers and aerators, parts 1 and 2 under Title 17 of California Code of Regulations, sections 93108 and 93108.5 (17 CCR, sections 93108 and 93108.5).

11. The operator shall comply with all requirements specified in the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations under Code of Federal Regulations, Title 40, Part 63 subpart O (40 CFR 63, subpart O).

12. Records shall be maintained to demonstrate compliance with conditions 4, 5, 6 and 7. The records shall be kept for at least two years and made available to AQMD personnel upon request.

NOTICE

In accordance with Rule 206, this Permit to Operate or copy shall be posted on or within 8 meters of the equipment.

This permit does not authorize the emission of air contaminants in excess of those allowed by Division 26 of the Health and Safety Code of the State of California or the applicable Rules and Regulations of the South Coast Air Quality Management District (SCAQMD). This permit cannot be considered as permission to violate existing laws, ordinances, regulations or statutes of other government agencies.

Executive Officer

Dorris M Bailey

By Dorris M.Bailey/JY02
8/21/2015

ORIGINAL

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT
21865 East Copley Drive, Diamond Bar, CA 91765

PERMIT TO OPERATE

Permit No.
R-D87020
A/N 298970
Page 1

This initial permit shall be renewed by ANNUALLY unless the equipment is moved, or changes ownership. If the billing for annual renewal fee (Rule 301.f) is not received by the expiration date, contact the District.

Legal Owner **ID 103609**
Or Operator: PACESETTER INC., A ST JUDE MEDICAL CO
ATTN: C.K. STODDARD, FACILITY ENGINEER
15900 VALLEY VIEW COURT
P.O. BOX 9221
SYLMAR, CA 91392-9221

Equipment located at: SAME AS ABOVE

Equipment Description:

AIR POLLUTION CONTROL SYSTEM CONSISTING OF:

1. CATALYTIC OXIDIZER/ABATOR, DONALDSON, 7' W. X 5' H. X 21' L. WITH A 80 KW PREHEATER, A HEAT EXCHANGER, A PREFILTER, AND FOUR DCI SURE-SORBER CATALYTIC FILTERS.

2. EXHAUST SYSTEM WITH A 1000 SCFM CENTRIFUGAL AIR BLOWER VENTING THREE ETHYLENE OXIDE STERILIZING SYSTEMS.

Conditions:

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN COMPLIANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.

2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.

3. ONLY ONE STERILIZER MAY VENT ITS PRIMARY ETHYLENE OXIDE EXHAUST TO THE CATALYTIC OXIDIZER/ABATOR AT ANY ONE TIME.

4. THE TEMPERATURE OF THE EXHAUST FROM THE CATALYST BED SHALL BE MAINTAINED BETWEEN 300 DEGREES F AND 500 DEGREES F AS INDICATED BY A PROPER TEMPERATURE GAUGE.

5. RECORDS SHALL BE MAINTAINED TO PROVE COMPLIANCE WITH CONDITION NO. 4. THE RECORDS SHALL BE MADE AVAILABLE TO THE DISTRICT UPON REQUEST.

ORIGINAL

PERMIT TO OPERATE

CONTINUATION OF PERMIT TO OPERATE

This Permit to Operate No. R-D87020 supersedes Permit to Operate No. D87020 issued on 12/09/94.

NOTICE

IN ACCORDANCE WITH RULE 206, THIS PERMIT TO OPERATE OR COPY SHALL BE POSTED ON OR WITHIN 8 METERS OF THE EQUIPMENT.

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EXECUTIVE OFFICER

Dorris M Bailey

By Dorris M. Bailey/gl
7/22/97

ORIGINAL

APPENDIX E - SOURCE TEST DATA

ECSi

"Your Regulatory Compliance Expert"

May 18, 2017

Ms. Sharanya Ganesh
Environmental Specialist
ABBOTT VASCULAR, INC.
15900 Valley View Court
Sylmar, California 91342

Subject: **RESULTS OF ETHYLENE OXIDE SOURCE TESTING PERFORMED AT ST JUDE MEDICAL, INC. IN SYLMAR, CALIFORNIA**

Dear Ms. Sharanya:

Please find attached a presentation of the results of the ethylene oxide source testing performed at your facility by ECSi, on Thursday, May 18, 2017. These test results are to be kept with all records pertaining to SCAQMD-required testing of the EtO gas-sterilization system, and are to be made available upon request by the SCAQMD. A copy of all raw test data, complete with sample chromatograms and calibration data, will be maintained in our files, and will be made available upon request.

The test results indicate that you continue to operate both of your EtO sterilization and emission-control systems in compliance with SCAQMD Rule 1405. I will follow up with you in approximately eleven months to let you know when your next annual source test is due.

The annual ethylene oxide emissions reported in Table 2 can be used for your facility's annual SCAQMD emissions report. If you have any questions or comments regarding this submittal, please contact me at (949)400-9145. We thank you for the opportunity to serve your needs.

Respectfully Submitted:

Daniel P. Kremer
ECSi

PO Box 848, San Clemente, California 92674 Phone: (949)400-9145 Fax: (949)281-2169 Email: dankremer@ecsi1.com

TABLE 1
ETHYLENE OXIDE CONTROL EFFICIENCY
OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE
OPERATED BY ABBOTT VASCULAR
IN SYLMAR, CALIFORNIA
ON MAY 18, 2017

CYCLE PHASE	INJECTION TIME	INLET ETO CONC. (PPM)(1)	OUTLET ETO CONC. (PPM)(2)	ETO CONTROL EFFICIENCY
Exhaust(3)	1242	1550	3.10	99.8000
Exhaust	1244	1740	3.13	99.8201
Exhaust	1246	3580	4.00	99.8883
Exhaust	1248	3470	2.85	99.9179
Exhaust	1250	2890	0.24	99.9917
Exhaust	1252	2850	2.20	99.9228
Exhaust	1254	2490	0.62	99.9751
Exhaust	1256	2300	0.01	99.9996
Exhaust	1258	2010	0.43	99.9786
Exhaust	1300	1870	0.54	99.9711
Exhaust	1302	1610	0.01	99.9994
Exhaust	1304	1330	0.01	99.9992
Exhaust	1306	1060	0.01	99.9991
Exhaust	1308	799.0	0.01	99.9987
TIME-WEIGHTED AVERAGE:		**2111**	**1.226**	**99.9473**
Aeration(4)	1310	879	0.01	99.9989
Aeration	1312	795	0.01	99.9987
Aeration	1314	617	0.01	99.9984
Aeration	1316	501	0.01	99.9980
Aeration	1318	368	0.01	99.9973
TIME-WEIGHTED AVERAGE:		**632.0**	**0.0100**	**99.9983**
		TIME-WEIGHTED AVERAGE COMBINED CONTROL EFFICIENCY:		**99.9579**
		SCAQMD REQUIRED COMBINED CONTROL EFFICIENCY:		**99.6**

Notes:
(1) - PPM = parts per million by volume
(2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
(3) - The exhaust phase started at 12:38, ended at 13:09.
(4) - The aeration phase started at 13:09, the first chamber evacuation was tested.

ECSi

South Coast
AIR QUALITY MANAGEMENT DISTRICT
21865 E. Copley Drive, Diamond Bar, CA 91765-4182
(909) 396-2000 http://www.aqmd.gov

Receipt Date: 06/02/2017 04:58:49 PM **Receipt Number:** 88252

Facility ID 103609
Name ST. JUDE MEDICAL CRMD
Address 15900 VALLEY VIEW CT

SYLMAR , CA 91342 -

Payment Details

Type	Check nbr	Amount	Check nbr	Amount	Amount
CASH	-	-	-	-	$.00
CHK	1583093	$3,927.10			
				Checks Total:	$3,927.10
				Total:	$3,927.10

Comments NEW

Received By AQMD Cashier

Signature _____

Duplicate Copy

20 Corporate Park | Suite 200 | Irvine, CA 92606 | P (949) 567-9880 | F (949) 567-9894
trinityconsultants.com

Trinity Consultants

VIA COURIER

June 2, 2017

South Coast Air Quality Management District
21865 E. Copley Drive
Diamond Bar, CA 91765

Subject: *Application for Permit to Construct an Ethylene Oxide Sterilizer*
Project No. 170501.0094

Facility: *St. Jude Medical, Inc.*
15900 Valley View Court
Sylmar, CA 91342
ID No. 103609

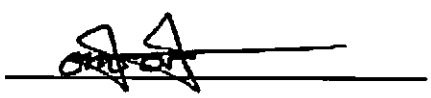
Dear Air Quality Engineer:

Please find enclosed an application for a Permit to Construct/Operate an ethylene oxide sterilizer, which includes air quality engineering evaluation, equipment specifications, site maps and other technical support documents. In addition, we have enclosed a check made payable to the SCAQMD in the amount of $3,927.10 to cover the application-processing fee.

Please call me with any questions or concerns. Thank you.

Sincerely,

TRINITY CONSULTANTS



Omar Elfar
Consultant

cc: Michael Larson, St. Jude Medical, Inc.

Encl.

AIR QUALITY ENGINEERING EVALUATION

St. Jude Medical, Inc. > Sylmar, CA

ST. JUDE MEDICAL

Application for Permit to Construct an Ethylene Oxide Sterilizer

Prepared By:

TRINITY CONSULTANTS
20 Corporate Park, Suite 200
Irvine, CA 92606

May 2017

Project No. 170501.0094

Trinity Consultants

Environmental solutions delivered uncommonly well

TABLE OF CONTENTS

1.0 FACILITY INFORMATION

Facility Name:	St. Jude Medical, Inc.
Facility ID:	103609
Facility Address:	15900 Valley View Court Sylmar, CA 91342
Mailing Address:	Same
Title V Facility:	No
RECLAIM:	No

2.0 EQUIPMENT DESCRIPTION

ETHYLENE OXIDE STERILZER NO. 2R, GETINGE, MODEL NO. GEE101420-1, 3' – 3.4" W. X 4' – 9.1" H. X 6' – 6.7" L., WITH A 100 KW ELECTRIC STEAM GENERATOR.

3.0 BACKGROUND

St. Jude Medical, Inc. (SJM) is submitting a permit application to construct an ethylene oxide sterilizer for the location described above, which is an existing SCAQMD facility. SJM is a Fortune 500 manufacturer of medical device products addressing various healthcare needs. Sold in over 100 countries, SJM's world class products address heart failure, heart rhythm disorders, vascular disease, chronic pain, movement disorders, and other human healthcare applications. SJM is seeking to permit one (1) sterilizer (as referenced above) at this site to replace the current Getinge Sterilizer No. 2 (Permit No. G22027), as referenced in Appendix D. The new Getinge sterilizer will be used alongside the other two ethylene oxide sterilizers (Permit Nos. G22028 and G37118) which are currently vented to a catalytic oxidizer (Permit No. R-D87020). This is a functionally identical source replacement project where there is no increase in the potential to emit.

The SJM Sylmar site manufactures implantable cardiac medical devices (pacers, implantable cardioverter defibrillators, and high and low voltage leads). Upon completing the manufacturing process, SJM sterilizes the implantable cardiac medical devices and associated packaging with 100% ethylene oxide in accordance with Food and Drug Administration (FDA) requirements and plant certifications. Similar to the current sterilizers, the new Getinge sterilizer will be operated under the same operating conditions and will be controlled by the same catalytic oxidizer. Existing permits allow ethylene oxide usage of sixteen (16) pounds per day, and four thousand (4,000) pounds per year. The new construction will not result in an increase of ethylene oxide usage from existing permitted levels.

The facility has not been issued any notice of violation or notice to comply by the District in the last two years. Also, the facility has not been cited for any public nuisance or visible emission complaints by the District in the last two years. This facility is located in an industrial and commercial area and there are no schools located within 1,000 feet from this facility (refer to Figure 1, Appendix B). In addition, there are no emission increases for VOC and therefore Rule 212 public notice is not required for this project.

4.0 PROCESS DESCRIPTION

All sterilizers are enclosed within a fire/explosion proof sterilization room. This room is monitored with two (2) baseline ethylene oxide leak detection systems. The catalytic oxidizer controls emissions from the sterilization room and sterilizers. Complete aeration of each sterilization load will also occur inside the sterilizers. A typical sterilization load contains varying quantities of pacers, defibrillators and leads. Pacers and defibrillators have an exterior construction consisting of a titanium enclosure with an epoxy connector top. Lead construction consists of silicone tubing over a metal conductor with a connector that fits into the pacer or defibrillator connector on one end, and a metal electrode on the other. Pacers, defibrillators, and leads are packaged and sealed in two (2) vacuum formed polymer trays. The vacuum formed polymer trays are sterilized with 100% ethylene oxide prior to shipment to customer locations.

4.1. Sterilization Process

The sterilizers are charged with 100% ethylene oxide. Each batch will experience a 24-hour sterilization cycle, which is comprised of the following sequence of operational events:

- The chamber is pre-heated by recirculating internal air for approximately 30 minutes.
- The chamber is evacuated by a vacuum pump until a pre-set pressure is attained.
- The chamber is held under vacuum for approximately 10 minutes to determine if any leaks exist.
- Compressed nitrogen gas is admitted to the chamber. The chamber is evacuated, and charged again with nitrogen gas for a pre-set number of pulses.
- The chamber is humidified with pulse injections of steam.
- The chamber is held at a specific temperature and humidity for a specified time period.
- Ethylene oxide is charged to the chamber until a specified pressure is attained. Nitrogen gas is charged to the chamber until a specified pressure is attained.
- Chamber pressure is maintained for specified sterilization period.
- Chamber gases are exhausted to a catalytic oxidizer where ethylene oxide is oxidized into carbon dioxide and water.
- The chamber is evacuated to a specified pressure. Nitrogen gas is charged to the chamber. This step is repeated, along with the previous step, at least 2 additional times.
- Complete chamber aeration commences by alternating vacuum and air purges.
- Air is admitted to the chamber through bacterial retentive 0.2 micro air filters until ambient atmospheric pressure is achieved.

The sterilization chamber is heated by recirculating water through interior jackets. A 100 kW electric steam generator supplies steam to the sterilization system.

4.2. Emission Control System

Exhaust air from the sterilization room and sterilizers is controlled with a catalytic oxidizer (also known as an "abator"). The abator contains four (4) catalytic filters containing a precious metal catalyst mixture of manganese dioxide and copper oxide. Oxidation of the ethylene oxide occurs as follows:

$$2C_2H_4O + 5O_2 \longrightarrow 4CO_2 + 4H_2O + \text{heat}$$

There is a preheat cycle of approximately 45 minutes to bring the system to an operating temperature of 300 degrees Fahrenheit (after initial startup, the system will operate continuously). The fan motor and heater are energized and the dampers are positioned in the preheat mode. The warm air heats up the catalytic beds. When the sensor on the catalytic beds sense a temperature of 280 degrees Fahrenheit, the system will end the preheat cycle and open the ethylene oxide feed valve. The heater is rarely used to maintain the operating temperature of the abator since the oxidation process is an exothermic reaction.

Air from the sterilization room and sterilizers is drawn through the abator by a 1000 scfm centrifugal fan. Prefilters remove any particulate matter from the inlet air. Abator exhaust air passes through a heat exchanger, heating coils and the catalytic beds. A portion of the exhaust air is recirculated to the hot side of the recuperative heat exchanger to preheat incoming air. The volume of airflow directed to the heat exchanger will vary depending upon the temperature of the catalytic beds. An abator temperature control switch will close the valve from the sterilization chamber and sterilizers to the vacuum pump, as the vacuum pump will not activate if the catalytic bed temperature rises above 500 degrees Fahrenheit.

Safety mechanisms are designed into the control system which close the inlet valve from the sterilization room and sterilizers, unless the following criteria are met: (1) catalytic bed temperature is at least 300 degrees Fahrenheit; (2) catalytic bed temperature is below 500 degrees Fahrenheit; (3) minimum air flow rate of 900 scfm; and (4) safety blow out pan is sealed.

Operating Hours:

Average: 24 hr/day, 5 day/week, 52 weeks/year
Maximum: 24 hr/day, 7 day/week, 52 weeks/year

5.0 EMISSION CALCULATIONS

There are no emissions of NOx, SOx, CO or PM from the sterilization equipment. The new sterilizer will operate under the existing permitted daily and annual ethylene oxide limits of 16 lbs/day and 4,000 lbs/year, respectively. The Rule 1405 source test recently conducted in May 2017 demonstrated a destruction efficiency of 99.9579% for the existing catalytic oxidizer (refer to Appendix E). Since product aeration also occurs within the sterilization chamber, capture efficiency for ethylene oxide is 100%. Therefore, a conservative control efficiency of 99.9% shall be used for VOC and air toxic emission calculations, as shown below.

5.1. VOC Emissions

The only VOC emissions from the subject equipment will be uncontrolled ethylene oxide. Applying the existing permit limits for ethylene oxide usage, the following VOC emissions are estimated assuming 99.9% control efficiency:

- MDU (Maximum Daily Uncontrolled) = 16 lbs/day
- MDC (Maximum Daily Controlled) = MDU x (1-C.E.) = 16 lbs/day x (1-99.9%) = 0.016 lbs/day
- 30DAC (30 Day Average Controlled) = MDU x (22 day/30 day) = 0.012 lbs/day
- AHU (Average Hourly Uncontrolled) = 16 lbs/day x 1 day/24 hours = 0.67 lbs/hr
- AHC (Average Hourly Controlled) = AHU x (1-Control Efficiency) = 0.67 x (1-99.9%) = 0.0007 lbs/hr
- MHU (Maximum Hourly Uncontrolled) = AHU = 0.67 lbs/hr
- MHC (Maximum Hourly Controlled) = AHC = 0.0007 lbs/hr
- AAC (Average Annual Controlled) = MDC x (260 days/yr) = 0.016 lbs/day x 260 = 4.16 lbs/yr

5.2. Air Toxic Emissions and Risk Calculations

Since ethylene oxide is a compound identified as a toxic air contaminant in Rule 1401, as amended October 7, 2016, the sterilizer emission source is subject to rule requirements. SCAQMD Rules 1401/212 Risk Assessment Procedures (Version 8.0) are applied for purposes of health risk screening and air toxics evaluations, as shown below.

Source and Receptor Data

- Max Uncontrolled = 4,000 lbs/yr = 2 tons/yr
- Max Controlled = 2 tons/yr x (1-99.9%) = 0.002 tons/ yr
- Resident Receptor Distance = ~100 m (Conservative Estimate; Refer to Figure 2, Appendix B)
- Worker Receptor Distance = ~100 m (Conservative Estimate; Refer to Figure 2, Appendix B)
- Stack Height = 46 ft (From Ground Level to the Top of the Stack)

Equations: TAC Screening (Tier 1)

Reference: SCAQMD Rules 1401/212 Risk Assessment Procedures, Version 8.0

Ethylene Oxide is a Chronic TAC, therefore the maximum annual emissions will be compared to the Screening Levels in Table 1.1.

Max Controlled = 4,000 lbs/yr x (1-99.9%) = **4 lbs/yr > 1.13 lbs/yr**

⇨ Tier 1 Screening Level exceeded. Therefore, Tier 2 Screening will be assessed.

Equations: MICR Screening (Tier 2)

Reference: SCAQMD Rules 1401/212 Risk Assessment Procedures, Version 8.0

EQN (1) $MICR = CP \times D \times 10^{-6}$

MICR = Maximum Individual Cancer Risk
CP = Cancer Potency
D = Dose

Where,

EQN (2) $D = Concentration \times Exposure$
EQN (3) $Concentration = GLC = (Q_{tpy} \times X/Q) \times MWAF$
EQN (4) $Exposure_R = CEF_R \times MP_R$
EQN (5) $Exposure_W = CEF_W \times MP_W \times WAF$

GLC = Ground Level Concentration
Q_{tpy} = Maximum Emission Rate (tons/yr)
X/Q = Concentration at a receptor distance / Emission Rate [(µg/m³)/(tons/yr)]
MWAF = Molecular Weight Adjustment Factor
Exposure = Receptor Exposure (Residential/Worker)
CEF = Combined Exposure Factor (Residential/Worker)
MP = Multi-pathway Factor (Residential/Worker)
WAF = Worker Adjustment Factor

Therefore,

$MICR_R = CP \times Q_{tpy} \times X/Q \times CEF_R \times MP_R \times 10^{-6} \times MWAF$
$MICR_W = CP \times Q_{tpy} \times X/Q \times CEF_W \times MP_W \times WAF \times 10^{-6} \times MWAF$

MICR Calculations – Residential Receptor (Tier 2)

CP = 3.10×10^{-1} (Table 8.1)
Q_{tpy} = Maximum Controlled = 0.002 tons/yr
X/Q = 4.02 (Table 3.2 for 100 m downwind distance and Burbank Station)
MWAF = 1 (Table 8.1)
CEF_R = 676.63 (Table 9.1)
MP_R = 1.0 (Table 8.1)

$MICR_R = (3.10 \times 10^{-1}) \times 0.002 \times 4.02 \times 676.63 \times 1.0 \times 10^{-6} \times 1 =$ **1.69×10^{-6}**

MICR Calculations – Worker Receptor (Tier 2)

CP = 3.10×10^{-1} (Table 8.1)
Q_{tpy} = Maximum Controlled = 0.002 tons/yr
X/Q = 4.02 (Table 3.2 for 100 m downwind distance and Burbank Station)
MWAF = 1 (Table 8.1)

CEF_W	= 56.26 (Table 9.2)
MP_W	= 1.0 (Table 8.1)
WAF	= 1.0 (Table 10.2)

$MICR_W = (3.10 \times 10^{-1}) \times 0.002 \times 4.02 \times 56.26 \times 1.0 \times 1.0 \times 10^{-6} \times 1 =$ **1.40×10^{-7}**

Since $MICR_R > MICR_W$, $MICR_R$ will be assessed against the T-BACT MICR level because the catalytic oxidizer control equipment is T-BACT.

MICR = $1.69 \times 10^{-6} < 10 \times 10^{-6}$ (T-BACT) => Rule 1401 MICR requirement is satisfied.

Equations: HIC Screening (Tier 2)

Reference: SCAQMD Rules 1401/212 Risk Assessment Procedures, Version 8.0

EQN (6) $HIC_{NS} = [Q_{tpy} \times (X/Q) \times MP \times MWAF]/Chronic\ REL$

HIC_{NS}	= Chronic Hazard Index – Nervous System Target Organ (Table 11.1)
Q_{tpy}	= Maximum Emission Rate (tons/yr)
X/Q	= Concentration at a receptor distance / Emission Rate [($\mu g/m^3$)/(tons/yr)]
MP	= Multi-pathway Factor
MWAF	= Molecular Weight Adjustment Factor
Chronic REL	= Chronic Reference Exposure Level

HIC Calculations – Residential Receptor (Tier 2)

Q_{tpy}	= Maximum Controlled = 0.002 tons/yr
X/Q	= 4.02 (Table 3.2 for 100 m downwind distance and Burbank Station)
MP	= 1.0 (Table 8.1)
MWAF	= 1 (Table 8.1)
Chronic REL	= 3.00×10^1 (Table 8.1)

$HIC_{NS} = (0.002 \times 4.02 \times 1.0 \times 1)/(3.00 \times 10^1) =$ **2.68×10^{-4}**

The value would be the same for the worker receptor as the parameter values are unchanged.

Therefore,

$HIC_{NS} = 2.68 \times 10^{-4} < 1.0$ => Rule 1401 HIC requirement is satisfied.

Equations: Cancer Burden Screening (Tier 2)

Reference: SCAQMD Rules 1401/212 Risk Assessment Procedures, Version 8.0

EQN (7) Cancer Burden = TRP x MICR

TRP	= Total Residential Population in the Zone of Impact
MICR	= Maximum Individual Cancer Risk

Since no census data is available, a residential population density of 7,000 persons/km^2 will be used in the TRP calculation (SCAQMD Rules 1401/212 Risk Assessment Procedures).

EQN (7)	TRP = 7,000 persons/km^2 x Zone of Impact
EQN (8)	Zone of Impact = 3.14 x R^2

The radius R is the distance between the equipment and the point at which the risk falls below one in one million.

EQN (9) R = Distance where $X/Q = (1 \times 10^{-6}) / (CP \times Q_{tpy} \times CEF \times MP \times 10^{-6} \times MWAF)$

X/Q	= Concentration at a receptor distance / Emission Rate [(µg/m^3)/(tons/yr)]
CP	= Cancer Potency
Q_{tpy}	= Maximum Emission Rate (tons/yr)
MWAF	= Molecular Weight Adjustment Factor
CEF	= Combined Exposure Factor (Residential)
MP	= Multi-pathway Factor (Residential)

Cancer Burden Calculations (Tier 2)

CP	= 3.10 x 10^{-1} (Table 8.1)
Q_{tpy}	= Maximum Controlled = 0.002 tons/yr
MWAF	= 1 (Table 8.1)
CEF_R	= 676.63 (Table 9.1)
MP_R	= 1.0 (Table 8.1)

Therefore,

$X/Q = (1 \times 10^{-6}) / (3.10 \times 10^{-1} \times 0.002 \times 676.63 \times 1.0 \times 10^{-6} \times 1) = 2.38$

Using linear interpolation:

R = 160.34 m (at X/Q = 2.38)

Therefore,

Cancer Burden = TRP x MICR = $[7{,}000 \times 3.14 \times (160.34/1000)^2] \times 1.69 \times 10^{-6} = 9.53 \times 10^{-4}$

Cancer Burden = $9.53 \times 10^{-4} < 0.5$ => Rule 1401 Cancer Burden requirement is satisfied.

⇨ **Tier 2 Screening Level is satisfied.**

6.0 SCAQMD RULE EVALUATIONS

6.1. Rule 212 - Public Notification

- **Rule 212 (c)(1)** – This section requires a public notice for all new or modified permit units that may emit air contaminants located within 1,000 feet from the outer boundary of a K-12 school. This source is not located within 1,000 feet from the outer boundary of a school (refer to Figure 1, Appendix B). Therefore, public notice will not be required by this section.

- **Rule 212 (c)(2)** – This section requires a public notice for all new or modified facilities which have on-site emission increases exceeding any of the daily maximums specified in subdivision (g). As shown in the following table, the emission increases from this project are below the daily maximum limits specified by Rule 212(g). Therefore, this application will not be subject to this section.

LB/DAY	CO	NOX	PM_{10}	ROG	Lead	SOX
MAX. LIMIT	220	40	30	30	3	60
INCREASES	0	0	0	0	0	0

- **Rule 212 (c)(3)** – There will be no increases in emissions of toxic air contaminants. Therefore, public notice will not be required by this section.

- **Rule 212 (g)** – This section requires a public notice for all new or modified sources which undergo construction or modifications resulting in an emissions increase exceeding any of the daily maximum specified in the table below. As shown in the following table, the emission increases from this project are below the daily maximum limits specified by Rule 212(g). Therefore, public notice will not be required by this section.

LB/DAY	CO	NOX	PM_{10}	ROG	Lead	SOX
MAX. LIMIT	220	40	30	30	3	60
INCREASES	0	0	0	0	0	0

6.2. Regulation IV - Prohibitions

- **Rules 401 and 402** – AQMD database has no records of any visible emissions or nuisance complaints against this company. Compliance with these requirements is expected with proper operation and maintenance of the equipment.

- **Rules 404 and 405** – As discussed in this evaluation, there are negligible to zero particulate emissions from the sterilizer. Therefore, this facility is expected to comply with these requirements.

6.3. Regulation XI - Source Specific Rules

- **Rule 1171** – SJM complies with the solvent cleaning operations requirements and limits under the category for Medical Devices and Pharmaceuticals.

6.4. Regulation XIII - New Source Review

- **Rule 1303 (a), Best Available Control Technology** – VOC emissions are greater than 1 pound per day from the sterilizers combined based on the calculations above. Therefore, BACT is triggered for this pollutant. The catalytic oxidizer is considered BACT for the sterilizer equipment, and also considered T-BACT for the control of ethylene oxide emissions.

- **Rule 1303 (b)(1), Modeling** – No detailed modeling analysis is required for VOC as per Rule 1304 (a)(1) exemption. There are no emissions of NOx, CO, PM10, or SOx.

- **Rule 1303 (b)(2), Emission Offsets** – This project is exempt from emission offsets requirements as per Rule 1304 (a)(1). The current sterilizer is being replaced with a functionally identical source, the potential to emit is unchanged, and current BACT is still applied, therefore emission offsets are not required for this project.

- **Rule 1303 (b)(3), Sensitive Zone Requirements** – SJM is located within Zone 1 of the SCAQMD jurisdiction. As mentioned previously, Rule 1304 (a)(1) exempts this project from any required emission offsets.

- **Rule 1303 (b)(4), Facilities Compliance** – The facility is currently in compliance with all applicable District rules and regulations.

- **Rule 1303 (b)(5), Major Polluting Facilities** – The requirements for major polluting facilities do not apply to this application because (1) the construction of a new facility is not being proposed; and (2) a major modification to this facility is not being proposed.

6.5. Regulation XIV - Toxics New Source Review

- **Rule 1401 (d)(1), (d)(2), (d)(3), Health Risk Standards** – Unless otherwise exempted by rule, Rule 1401 specifies health risk standards for MICR, HIC, HIA and cancer burden that apply to new, modified or relocated permit units with emissions of listed Rule 1401 air toxics. For this project, the use of the existing catalytic oxidizer is considered T-BACT for the sterilization equipment. In addition, based upon the risk calculations provided in Section 5 of this evaluation, the MICR resulting from the controlled sterilization system is less than ten in one million, and HIC (HIA is not applicable for ethylene oxide) does not exceed the 1.0 limit, which complies with Rule 1401.

- **Rule 1401 (d)(5), Federal New Source Review for Toxics** – Rule 1401 also prohibits the construction or reconstruction of a major stationary source emitting hazardous air pollutants listed in Section 112 (b) of the CAA, unless the source is constructed with Best Available Control Technology for Toxics (T-BACT) and complies with all other applicable requirements referenced in 40 CFR 63.40 through 63.44. While the facility does employ T-BACT for its sterilization operations, this facility is not a major stationary source of HAPs, and therefore these provisions would not apply.

- **Rule 1401 (g)(1)(C), Exemption for Functionally Identical Replacement** – Rule 1401 exempts functionally identical replacements from the health risk standards referenced above, provided there is no increase in maximum rating or increase in emissions of any toxic air contaminants. For this project, the new sterilizer is replacing a functionally identical sterilizer unit with no increase in maximum rating or increase in emissions (as the existing permit limits will remain the same).

- **Rule 1405 (d)(2)(D), Control Efficiency** – Since ethylene oxide usage equals or less than 4,000 lbs per year, Rule 1405 (d)(2) is applicable. This equipment complies with the control requirements of this section since emissions from sterilization chambers, aeration and back-draft are controlled with a catalytic oxidizer with a control efficiency of 99.9579% based on the most recent source test. It is above the required combined efficiency of 99.6%.

- **Rule 1405 (d)(6), Source Tests** – SJM conducts annual source tests on the catalytic oxidizer to ensure compliance with this requirement. The most recent annual source test was completed in May 2017 (refer to Appendix E).

- **Rule 1405 (d)(9), Ethylene Oxide Diluents** – SJM utilizes 100% ethylene oxide as its sterilant gas. No chlorofluorocarbon diluents are used.

- **Rule 1405 (e), Recordkeeping** – SJM maintains records to demonstrate the (a) number of sterilizer cycles and (b) the pounds of ethylene oxide used per cycle for each sterilizer per day.

- **Rule 1405 (f)(2), Leak Test** – Leak detection is performed in the following manner. First, a 10-minute leak test is performed on the sterilizer chamber under vacuum conditions every cycle. Second, a similar 3 hour leak test under vacuum conditions is performed semi-annually. Third, a continuous leak detection system monitors the ethylene oxide concentration levels within the sterilization room.

7.0 FEDERAL REQUIREMENTS

Ethylene oxide sterilization facilities are subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP), Subpart O: Ethylene Oxide Emissions Standards for Sterilization Facilities. Pursuant to 40 CFR §63.361(f), since this facility is not a major stationary source of HAPs, only those federal requirements applicable to area sources would apply.

- **§63.362 Standards** – The equipment complies with the control standards of section §63.362(c), as emissions from sterilization chambers, aeration and back-draft are controlled with a catalytic oxidizer with a control efficiency of 99.9579%, based on the most recent source test.

- **§63.363 Compliance and performance provisions** – The facility complies with the minimum temperature requirement of §63.363(b)(3), and maintains the temperature of the catalyst bed within the range mandated by the SCAQMD permit. In addition, the facility performs a source test for the catalytic oxidizer once per year as per §63.363(b)(4)(i).

- **§63.364 Monitoring requirements** – The facility complies with the monitoring requirements of this section, more specifically, the ethylene oxide usage and the temperature values. The temperature recorder is calibrated at least semi-annually.

- **§63.366 Reporting requirements** – The facility produces a compliance report of the sterilization system semi-annually to the EPA and to the district, displaying the ethylene oxide usage and the compliance status of the sterilization system. In the case of deviations from the requirements of this section, or of the district or the permit, the facility will notify the EPA and the district within 30 days following the end of each calendar half or quarter as appropriate.

- **§63.367 Recordkeeping requirements** – The temperature and ethylene oxide usage records, source tests, catalyst replacement documentation, and other necessary records are stored and available upon request.

8.0 RECOMMENDATIONS

It is recommended that the Permit to Construct is issued with the following equipment descriptions and operating conditions:

Equipment Description:

ETHYLENE OXIDE STERILZER NO. 2R, GETINGE, MODEL NO. GEE101420-1, 3' – 3.4" W. X 4' – 9.1" H. X 6' – 6.7" L., WITH A 100 KW ELECTRIC STEAM GENERATOR.

Operating Conditions:

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THIS APPLICATION UNDER WHICH A PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.

2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.

3. THIS EQUIPMENT SHALL NOT BE OPERATED UNLESS IT IS VENTED TO THE ETO CONTROL DEVICES THAT ARE IN COMPLIANCE WITH THE AQMD RULE 1405 AND HAVE BEEN ISSUED PERMIT TO CONSTRUCT OR OPERATE BY THE AQMD.

4. THE TOTAL ETHYLENE OXIDE (ETO) USED IN THIS FACILITY SHALL NOT EXCEED 4,000 POUNDS IN ANY ONE CALENDAR YEAR.

5. THE TOTAL ETHYLENE OXIDE (ETO) USED IN THIS FACILITY SHALL NOT EXCEED 16 POUNDS IN ANY ONE DAY.

6. A DAILY LOG INDICATING THE DATE, THE STERILIZATION CHAMBER IDENTIFICATION NUMBER, THE STERILIZATION CYCLE START-UP AND COMPLETION TIME, THE TIME OF THE DAY WHEN THE CHAMBER IS PURGED, AND POUNDS OF ETO USED FOR EACH STERILIZATION CYCLE SHALL BE MAINTAINED FOR EACH ETO STERILIZATION CHAMBER.

7. THIS EQUIPMENT AND ALL THE DEVICES AND COMPONENTS WHICH ARE CONNECTD TO THIS EQUIPMENT SHALL BE LEAK TESTED EVERY SIX MONTH USING THE LATEST CARB TEST METHOD DURING CONDITIONS OF MAXIMUM STERILANT GAS USE.

8. THERE SHALL BE NO STAGING OF STERILIZED PRODUCTS IN UNCONTROLLED AREAS OF THE PLANT. ANY TEST OR BIO INDICATOR REMOVAL SHALL BE CONDUCTED IN AN ENCLOSED LOCATION THAT IS VENTED TO AN ETO CONTROL EQUIPMENT.

9. THE VALVES ON ETHYLENE OXIDE DRUMS SHALL BE COMPLETELY CLOSED WHEN NOT IN USE. IF CLOSING OF A DRUM VALVE CANNOT CONTAIN ETO, OR IF THERE IS AN INDICATION OF ETO LEAK FROM ANY OTHER PART OF AN ETO DRUM, THE DRUM SHALL BE IMMEDIATELY MOVED TO AREA THAT IS VENTED TO AN ETO CONTROL EQUIPMENT.

10. THE OPERATOR SHALL COMPLY WITH ALL REQUIREMENTS SPECIFIED IN THE ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MESASURE (ATCM) FOR STERILIZERS AND AERATORS, PARTS 1 AND 2 UNDER TITLE 17 OF CALIFORNIA CODE OF REGULATIONS, SECTIONS 93108 AND 93108.5 (17 CCR, SECTIONS 93108 AND 93108.5).

11. THE OPERATOR SHALL COMPLY WITH ALL REQUIREMENTS SPECIFIED IN THE NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAP) FOR ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS UNDER CODE OF FEDERAL REGULATIONS, TITLE 40, PART 63 SUBPART O (40 CFR 63, SUBPART O).

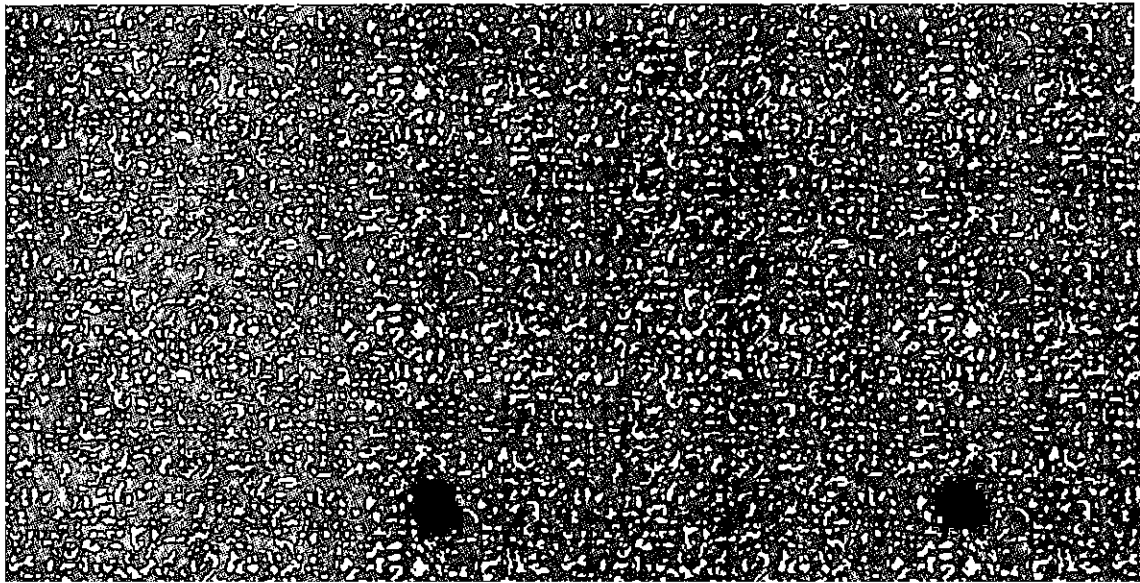
12. RECORDS SHALL BE MAINTAINTED TO DEMONSTRATE COMPLIANCE WITH CONDITIONS 4, 5, 6 AND 7. THE RECORDS SHALL BE KEPT FOR AT LEAST TWO YEARS AND MADE AVAILABLE TO AQMD PERSONNEL UPON REQUEST.

APPENDIX A - SCAQMD APPLICATION FORMS

39069 SOUTH COAST AIR QUALITY MANAGEMENT CHECK NO:1583093 DATE:05/16/2017

VOUCHER	INVOICE	GROSS AMOUNT	DISCOUNT	NET AMOUNT
1900313163	PERMIT APP Facility ID: 103609	3,927.10	0.00	3,927.10
		3,927.10	0.	3,927.10

REMOVE SIDE EDGES FIRST
TO OPEN - FOLD AND TEAR ALONG PERFORATION



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